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THE SAFETY OF FOOD IMPORTS: FROM THE FARM TO THE TABLE—A CASE STUDY OF TAINTED IMPORTED FRUIT

HEARING

BEFORE THE

PERMANENT
SUBCOMMITTEE ON INVESTIGATIONS

OF THE

COMMITTEE ON
GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

ONE HUNDRED FIFTH CONGRESS

SECOND SESSION

PART II

JULY 9, 1998

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THE SAFETY OF FOOD IMPORTS: FROM THE FARM TO THE TABLE—A CASE STUDY OF TAINTED IMPORTED FRUIT—PART II

THURSDAY, JULY 9, 1998

U.S. SENATE,
PERMANENT SUBCOMMITTEE ON INVESTIGATIONS,
OF THE COMMITTEE ON GOVERNMENTAL AFFAIRS,
Washington, DC.

The Subcommittee met, pursuant to notice, at 9:31 a.m., in room SD–342, Dirksen Senate Office Building, Hon. Susan M. Collins, Chairman of the Subcommittee, presiding.

Present: Senators Collins, Cochran, Levin, Lieberman, and Durbin.

Staff Present: Timothy J. Shea, Majority Chief Counsel and Staff Director; Mary D. Robertson, Chief Clerk; Don Mullinax, Chief Investigator; Eric Eskew, Investigator (Detailee, HHS–IG); Lindsey E. Ledwin, Staff Assistant; Kirk E. Walder, Investigator; Dr. Stephanie A. Smith, Investigator (Congressional Fellow); Beth Stein, Counsel to the Minority; Brian Benczkowski (Senator Domenici); Butch Burke (Senator Stevens); Pam Muha (Senator Specter); Michael Loesch (Senator Cochran); Maggie Hickey (Senator Thompson); Felicia Knight and Steve Abbott (Senator Collins); Kevin Mulry and Marianne Upton (Senator Durbin); Antigone Potamianus (Senator Levin); Doug O'Malley and Kevin Landy (Senator Lieberman); and Lynn Kimmerly and Donna Berry (Senator Cleland).

OPENING STATEMENT OF SENATOR COLLINS

Senator COLLINS. Good morning. The Subcommittee will please come to order.

Today the Permanent Subcommittee on Investigations holds its second in a series of hearings on the safety of imported food. Food safety is a serious and growing public health concern. The escalation in the number of foodborne illnesses at a time when food imports are soaring prompted the Subcommittee to focus its investigation on the safety of imported fruit and vegetables.

At the Subcommittee's first hearing in May, the General Accounting Office reported that as many as 81 million cases of foodborne illnesses and more than 9,000 related deaths are estimated to occur in the United States each year. The medical treatment and lost productivity resulting from foodborne illnesses costs billions of dollars a year.

We also learned that the system intended to protect Americans from tainted imported food is not effective. The General Accounting Office told the Subcommittee that "Federal agencies cannot ensure that the growing volume of imported food is safe for consumers." Specifically, the GAO reported that agencies have not targeted their resources on imported foods posing the greatest risks and concluded that the limited resources available to the Food and Drug Administration and the U.S. Department of Agriculture must be more efficiently deployed to better protect Americans from unsafe imported food.

In its report to the Subcommittee, the GAO also found that "weaknesses in controls over food imports enable entry of unsafe products." In other words, even if Federal inspectors discover tainted food, controls are not in place to prevent unsafe products from entering the marketplace and ending up on the dinner tables of America.

For example, during one U.S. Customs Service special operation, 70 percent of the food shipments that the FDA had ordered destroyed or re-exported because they were unsafe actually entered into the American marketplace.

As a continuation of the Subcommittee's investigation into the safety of imported food, our hearing today will examine a case study of tainted imported fruit. We will look at the food import system from the farm to the table and hear how a microscope organism made thousands of Americans sick in 1996 and 1997 from eating tainted raspberries.

In the spring of 1996 and 1997, as the chart before you shows,[1] people from Maine to California, in a total of 23 States and the District of Columbia, became sick. They experienced symptoms of foodborne illness. Many of these victims ate food at common events. This common link led public health officials to mobilize resources in an effort to determine the case of these illnesses.

We know the probable source of the 1996 and 1997 outbreaks because of the scientific traceback investigation conducted by public health officials, Federal regulatory agencies, and the Centers for Disease Control and Prevention. It is this fascinating and painstaking process—the traceback of a foodborne illness from the patient back to the source of contamination—that we will examine in the hearing this morning.

The Subcommittee's inquiry will focus on the following critical questions: How is fresh fruit produced and then imported into the United States? What are the ways in which produce can become contaminated? And how do the CDC and other public health agencies investigate outbreaks of foodborne illnesses to determine the source of contamination?

To assist the Subcommittee, we are fortunate to have a distinguished group of scientists here this morning. First, we will hear from Dr. Stephanie Smith. Dr. Smith is a food scientist by training and is currently working with the Subcommittee on a 1-year fellowship. As a Subcommittee investigator, she traveled to Guatemala to observe first-hand the production and exportation process for raspberries.

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[1] See Exhibit No. 1 which appears in the Appendix on page 44.

Second, we are pleased to have Dr. Jeffery Foran, an environmental scientist who himself became ill in 1996 after eating raspberries from Guatemala.

Finally, we will hear from CDC officials. Dr. Stephen Ostroff is an Associate Director at CDC's National Center for Infectious Diseases. Dr. Barbara Herwaldt is a CDC medical epidemiologist who led the Division of Parasitic Diseases team which investigated the 1996 *Cyclospora* outbreak. The CDC is the Federal agency to which many public health officials turn for scientific expertise when outbreaks of foodborne illnesses occur.

Let me also mention that I invited the Guatemalan Ambassador to the United States to submit a written statement describing improvements made to the Guatemalan production and expert process since the 1996 and 1997 *Cyclospora* outbreaks. This week, we received through the Guatemalan Embassy a written statement from the Guatemalan High Level Commission for Food Safety. This statement will be made a part of today's hearing record.[1]

I want to emphasize that this hearing is not intended to single out Guatemala. As the Guatemalan officials have indicated, considerable improvements have been made in that country's production process, and in fact it was Guatemala which voluntarily suspended the export of raspberries in 1997 after that fruit was identified as the cause of the *Cyclospora* outbreak. The Subcommittee's purpose is not to indict one country or region of the world but rather to focus on a case study of tainted imported fruit from the farm in a foreign country to the tables of America, in order to understand how we can better protect the American consumer.

The safety of food imports is literally a life and death issue for many people, especially our children and our elderly. As the vast majority of our food supply is safe, consumers should not stop eating imported fruit and vegetables. However, this country's food safety net must be improved so that consumers are protected from the risk of unsafe foods, particularly when contamination is not detectable by the average consumer.

The difficulty of this task is demonstrated by the fact that just 3 weeks ago, press reports described yet another serious outbreak of *Cyclospora*, this time in Canada, which may also prove to be caused by raspberries imported from Central America.

As we continue this important work, we are looking forward to hearing from our witnesses this morning in order to learn more about foodborne illnesses, how they occur, and how they can be prevented.

It is now my pleasure to recognize Senator Levin for any statement he may have.

OPENING STATEMENT OF SENATOR LEVIN

Senator LEVIN. Madam Chair, thank you, and thank you for holding this series of hearings. Your leadership is critically important. We all appreciate it, and the Nation is better off because of it.

Ensuring the safety of the Nation's food supply, both domestic and imported, should be a top priority for Congress. Americans are eating more and more imported food, especially imported produce. A recent GAO report noted that in 1980, 24 percent of the fruit consumed by Americans was imported and that by 1995, that number had increased by more than a third, to 33 percent. The same report shows that the percentage of vegetables imported had increased from 7 percent to 11 percent.

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[1] See Exhibit No. 6 which appears in the Appendix on page 57.

The fundamental importance of ensuring food safety was highlighted once again when an outbreak of hepatitis A in my home State of Michigan occurred last year. Hundreds of Michigan schoolchildren were sickened from eating tainted frozen strawberries imported from Mexico that had improperly and illegally found their way into the school lunch program.

Those who are least able to protect themselves, as our Chairman said, including women, children, and people with weakened immune systems, are the most vulnerable to foodborne illnesses.

I am happy that we recently passed S. 1150, a bill which included a number of important food safety elements that are similar to elements contained in companion bill which Representative Debbie Stabenow and I had previously introduced, including a provision that requires the Department of Agriculture to form a FEMA-like crisis management team to handle food poisoning outbreaks and other agriculture-related emergencies. These crisis management teams will integrate efforts with Federal, State and local agencies as well as with our colleges and universities and other research organizations and function quickly to limit the harmful effects of contaminated food.

As the volume of imported food, especially fruit and vegetables, continues to increase significantly while our Federal Government inspection resources remain the same, it is not surprising that the percentage of imported food shipments actually inspected has decreased. In other words, the FDA cannot keep pace with the increasing volumes of imported foods under its jurisdiction, namely, fruit, vegetables and grains.

In 1992, the FDA inspected 8 percent of imported foods. In 1997, it was only able to inspect 2 percent of imported foods. So we are going in the wrong direction.

At the first hearing on this subject, we learned that Federal inspection of imported foods is woefully inadequate. Enforcement is understaffed; remedies for violation of the food safety laws are weak. The President, as part of his Food Safety Initiative, has proposed that we provide the FDA with authority to require that imported foods be produced in foreign countries under food safety systems that are equivalent to those in the United States. He has also proposed increasing funding to enhance inspections by FDA personnel. I hope we will act on those measures promptly, hopefully in this Congress.

We must also strengthen legal remedies available to Federal inspectors by providing the Department of Agriculture with authority to mandate recalls of food under their jurisdiction and to increase fines that they can levy for food safety related violations.

The President has also asked Federal agencies to devise a plan for creating a National Institute for Food Safety Research and has directed the FDA to issue regulations that would require warning labels on fruit juice that has not been pasteurized or otherwise processed to kill bacteria.

The case study that the Subcommittee takes up today, like the issue of tainted frozen strawberries from Mexico that sickened children in Michigan, reflects great gaps and weaknesses in our Federal food safety scheme. We should provide the FDA equivalency authority. We should empower regulators to mandate recalls of tainted food. We should strengthen penalties for violating food safety laws, and hopefully, we should act in this Congress before more Americans are stricken by foodborne illnesses that could have been prevented had those fruit and vegetables been grown in the United States.

I want to again thank you, Madam Chairman, and thank our witnesses for their appearance today. I have to be at the Armed Services Committee as the senior Democrat there on an important hearing, so I will not be able to be here for this testimony, but I will surely follow it closely.

Senator COLLINS. Thank you, Senator Levin.

It is now my pleasure to recognize Senator Cochran, who is the Chairman of the Agriculture Appropriations Subcommittee, for any statement that he might have.

OPENING STATEMENT OF SENATOR COCHRAN

Senator COCHRAN. Thank you very much, Madam Chairman.

Let me first commend you for this series of hearings you are having and the investigation that is being conducted by this Permanent Subcommittee on Investigations. I am happy to be a Member of this Subcommittee, and I think it can be a very helpful and important contribution to our understanding more fully the problems of food safety in terms of inspection and detection. More complicated, and perhaps more important than any of this, is the question of which options we select to make a part of a reform effort to ensure that we do all that we possibly can to protect the safety and health of the consumers in America. That is the big challenge as I see it, and I hope that as we go through the process of looking at the facts that have been compiled by the Centers for Disease Control and other agencies and researchers, that we keep in mind that at some point, we have to confront the real challenge of coming up with a better system.

Obviously, efficiencies have to be introduced into our food safety and inspection system at the Department of Agriculture and at the Food and Drug Administration. Just giving the power to fine, the power to ban, to specific Federal agencies is not enough. We have disagreements now between those agencies as to which would be the more appropriate agency to have what authority, we have to cut through all of this internecine competition within the Federal agencies. We also have to confront the realities of possible retaliation from countries where bans may be imposed unilaterally, without any due process requirement, by a Federal agency. There are all kinds of problems that we have to understand before we make final decisions about how to improve the system that we have.

We need to work hard, and I think the conduct of this hearing shows how concerned this Congress is to get something done that makes sense, that is workable, that is affordable, and that serves the overriding interests of the consumers and the public in this country of ours.

We have the safest supply of food of any country in the world, and we have an enormous opportunity to import, because of our high standard of living, food from all over the world, and our consumers have a greater range and variety of fresh vegetables and produce and wholesome meat and poultry and seafood of any country in the world, and of this, we are very proud.

But we do have some serious problems, and they will be identified, and that is the purpose of this hearing, to find out the extent of the problems that we have now in terms of detecting contaminated food supplies, particularly from imported fruit and vegetables. Ensuring the safety of those foodstuffs comes under the jurisdiction of the Food and Drug Administration.

I am very glad to be here today, and I look forward to hearing the testimony and working closely with the other Members of this Committee to try to help come up with the best possible solution for dealing with the problems that we have.

Thank you.

Senator COLLINS. Thank you very much, Senator Cochran.

Senator Lieberman, it is a pleasure to have you here today as well.

OPENING STATEMENT OF SENATOR LIEBERMAN

Senator LIEBERMAN. Thank you, Madam Chairman, and thanks for conducting this very important series of hearings examining the safety of the food we eat. Thanks also to your staff for the high level of work that they have done on this.

In my first year in the Senate, 1989, I was involved in an investigation that the Environment and Public Works Committee did on pesticides in our foods. One of the things we found was that the FDA was letting into the country products that had been sprayed with pesticides that were illegal here. Another thing we found was that some American growers were using illegal pesticides on crops being grown for export.

Both of those practices were outrageous and unacceptable, and in time, Congress and the Executive Branch did something about it.

The problem of the safety of the food we eat, particularly the food that is imported, has become much worse since that first series of hearings I participated in in 1989 as it relates to imports, because, as we have indicated, the percentage of food that we eat that is imported has multiplied dramatically.

Let me read from a quote given to *The New York Times* by Dr. Robert Tauxe, Chief of the Foodborne and Diarrheal Disease Branch at the Centers for Disease Control. He said: “Go to a restaurant and take a look at your supper. How many different continents are on your plate?” We could say that for a lot of the meals we eat at home as well.

“The food chain that fills those plates has become unimaginably intricate,” and they cite as an example alfalfa sprouts, which gave salmonella to hundreds of people in 24 States in the last couple of years. The seeds for those sprouts were bought from Uganda and Pakistan, among other nations, they were shipped through the Netherlands, they were flown into New York, and they were trucked around the United States. That is why previously unknown pathogens are being discovered repeatedly and years after they arrive in the United States. It is one of the down sides of the global economy from which we have benefited in so many other ways.

So I think this series of hearing is critically important. I remember at the end of that series of hearings in 1989 saying that the party that you register with or the ideology that you hold does not affect the level of your concern about the safety of what you eat. I think that remains true. If there is anything that the public wants us to do, it is to act in areas like this, where they simply cannot act to protect themselves. We are a long way from the days when people used to grow most of the fruit and vegetables they ate right around where they lived. They come from all over the country, and now, from all over the world, and they need us to stand as best we can between them, their stomachs and the rest of the world that puts food on their table.

So I think there is a very broad public consensus that we do something about this. I particularly appreciate today, Madam Chair, that you are going to examine a case study, the cyclosporiasis outbreak, because I think it can help us bring into relief those things that the government is doing well along with the private sector and those things were are not doing well and, in some cases, are doing very badly.

I was quite impressed in reviewing the materials for this morning's hearing, this instance, by the excellent response of the CDC and our other public health officials to this fast-developing public health crisis. I know we are going to hear today about how they quickly traced seemingly isolated cases of a rare illness to a handful of raspberry farms in Guatemala.

It is a modern-day international epidemiological—and I might even add, gastrointestinal—Sherlock Holmes story. There is probably a movie here somewhere. But it is remarkable and quite impressive, and clearly one of the things that we do well to the benefit of all in our country. And in the case of the cyclosporiasis crisis, which affected about 40 people in the State of Connecticut, I want to offer my thanks to the CDC for what they did.

But among the things that we do not yet do well, as has been testified to, is to find a way to raise the level of protection of the food that we are importing. As I age, my memory may be somewhat faulty, but I remember a witness, I believe from the FDA—we were talking about how much inspection occurred of imported fruit—and he was referring to a shipment of bananas that had some problems with pesticides, and he referenced "two" inspections.

So I asked, "Of boatloads of bananas?"

"No."

"Of two boxes of bananas?"

"No."

I asked, "Two what?"

He said, "Two bananas."

Well, I may have the details of the story slightly off, but that is how poor it was then, and it is poorer now. As Senator Levin indicated, only 2 percent of imported foods are inspected by FDA.

So we continue to have what I would describe as a desperate need to give more authority to the FDA over imported fruit and vegetables and more people to exercise that authority, and I hope that some support for that emerges from these very important hearings that you are holding, Madam Chair.

I thank you for your leadership here, and I look forward to working with you and hearing the witnesses today.

Senator COLLINS. Thank you, Senator.

Due to time constraints, the Subcommittee was unable to accommodate everyone who wished to testify today. We will, however, be leaving the hearing record open for 10 days so that anyone who wishes to submit a written statement may do so.

In addition, without objection and for the convenience of all the Members, all exhibits, including the photographs and charts previously made available to Subcommittee Members, will be made part of the hearing record.

I would now like to ask our panel of witnesses to come forward. Our witnesses this morning will describe for us how outbreaks of foodborne illnesses are investigated and specifically examine the 1996 and 1997 outbreaks of *Cyclospora* associated with Guatemalan raspberries.

The first witness, Dr. Stephanie Smith, is currently an investigator who is on the temporary staff of the Permanent Subcommittee on Investigations. Dr. Smith has a doctorate in food science from Michigan State University and nearly 6 years of food industry experience with two international companies as well as a domestic food distributor. She has been working as an investigator for the Subcommittee since October 1997, and we have been very pleased to have her as part of our team.

As part of the Subcommittee's investigation, Dr. Smith traveled to Guatemala to observe first-hand the raspberry production and exportation process.

Our second witness, Dr. Jeffery Foran, is an environmental scientist and expert in quantitative risk assessment. Dr. Foran is the Executive Director of the Risk Science Institute in Washington, DC. The Risk Science Institute is a component of the International Life Science Institute, a nonprofit, worldwide foundation established in 1978 to advance the understanding of scientific issues related to nutrition, food safety, toxicology, risk assessment and environment. In addition to being a scientist, Dr. Foran was also a consumer who became ill after consuming Guatemalan raspberries, proving that no matter what your level of expertise, no one is immune to *Cyclospora*.

Finally, we will hear from two officials from the CDC, Dr. Stephen Ostroff and Dr. Barbara Herwaldt, who are both with CDC's National Center for Infectious Diseases. Dr. Ostroff is the Associate Director for Epidemiologic Science, and Dr. Herwaldt is a medical epidemiologist in the Division of Parasitic Diseases. Both have extensive experience in investigating and tracking infectious diseases and were involved in the *Cyclospora* case that we are examining today.

Pursuant to Rule 6, all witnesses who testify before the Subcommittee are required to be sworn in, and you have already stood for me, but please raise your right hands.

Do you swear that the testimony you are about to give to the Subcommittee will be the truth, the whole truth, and nothing but the truth, so help you, God?

Dr. OSTROFF. I do.

Dr. HERWALDT. I do.

Dr. SMITH. I do.

Dr. FORAN. I do.

Senator COLLINS. Thank you. Please be seated.

I am going to ask each of you, in the interest of time, to limit your oral testimony to about 10 minutes each. If you need a little longer, that is fine as well. We will be using a timing system this morning to assist you. Before the red light comes on, you will see the lights change from green to orange, and that will tell you that you have 1 minute left to wrap up your testimony. I want to assure you that your entire prepared testimony will be included in the record in its entirety.

Dr. Smith, please proceed, and again, thank you for all your assistance to the Subcommittee.

TESTIMONY OF DR. STEPHANIE A. SMITH, INVESTIGATOR, PERMANENT SUBCOMMITTEE ON INVESTIGATIONS, COMMITTEE ON GOVERNMENTAL AFFAIRS, U.S. SENATE

Dr. SMITH. I would like to thank Senator Collins for the opportunity to testify today before the Permanent Subcommittee on Investigations. I have a doctorate in food science from Michigan State University and nearly 6 years of food industry experience, as the Senator mentioned. I have been working as an investigator on the Permanent Subcommittee on Investigations since October of last year.

This morning, I will report to the Subcommittee the results of a case study which is part of the ongoing investigation conducted at the direction of Senator Collins. I will describe the process by which fruit grown abroad reaches American consumers, using raspberry production in Guatemala as an example.

Fresh Guatemalan raspberries have received considerable attention because of their association with outbreaks of an infection caused by *Cyclospora cayetanensis*, which occurred in the United States and Canada during the spring of 1996 and spring of 1997. *Cyclospora* is a protozoan parasite that causes a gastrointestinal illness called cyclosporiasis. This illness is typically characterized by watery diarrhea and other symptoms such as nausea, abdominal cramps, substantial weight loss and fatigue. If not treated, the illness can be severe and prolonged.

Prior to the 1996 outbreak, *Cyclospora* was relatively unknown in the United States. According to the scientific literature, only sporadic cases, mostly in travelers, and two small clusters of cyclosporiasis were recognized in North America. These clusters were associated with water, not food.

I would like to make two points. First, very strong epidemiological evidence implicates the source of cyclosporiasis outbreaks of spring 1996 and spring 1997 as fresh Guatemalan raspberries. However, neither the source of the contamination nor the point at which the contamination occurred is clear. One hypothesis is that raspberries became contaminated through spraying with insecticides and fungicides mixed with contaminated water. Other hypotheses consider soil, animals or humans as sources of the contamination on the farm.

Second, our investigation revealed that the Guatemalans, working with the Centers for Disease Control and Prevention and the Food and Drug Administration, have made considerable investments to upgrade their farm facilities and train their employees in proper agricultural, post-harvest handling, sanitation, personal hygiene and recordkeeping practices.

In late March of this year, as part of the Subcommittee's comprehensive investigation of the safety of food imports, I, along with the Subcommittee's chief investigator, spent 4 days in Guatemala. The purpose of our trip was threefold: (1) to meet with representatives who were involved in production and exportation of fresh raspberries; (2) to make first-hand observations of raspberry farms and packing facilities; and (3) to document the raspberry production process. Our trip included visits to two analytical laboratories, 10 berry farms, and a produce freezing facility.

My comments today will be based on our observations as well as information supplied by the CDC, the FDA, the U.S. Department of Agriculture, the U.S. Customs Service, and officials of the Guatemalan Government.

I would now like to walk through the process of raspberry production and distribution from a typical Guatemalan farm to an American table. As I stated, the mode of contamination of the fresh raspberries with *Cyclospora* remains unknown. However, I will highlight points in the generalized process at which the berries could have become contaminated. Keep in mind, that, in general, anything that comes in direct contact with the fruit, including water, soil and human hands, is potentially a source of contamination. My testimony will follow the flow diagram displayed here.[1]

For seedlings to become flowering plants requires approximately 6 months. Another 6 weeks is required for raspberries to be ready for harvest. This photograph[2] shows how raspberry plants are grown—typically, in hedgerows, supported by posts and wires. The plants are approximately 4 to 5 feet high and may or may not be tied to the wires individually, as shown here. The location of the fruit on the plant is at least 3 feet off the ground, and therefore, no direct contact occurs between the fruit and the soil. Soil is a possible vehicle of contamination, therefore, it is important that the soil not touch the fruit.

The plants are watered using drip irrigation. A drip irrigation system typically consists of a piece of plastic tubing running along the ground as shown in this photograph. The underside of the tubing has small holes so the ground can be wet slowly over a long period of time. Fertilizers, if used, are administered through the drip irrigation system. No direct contact occurs between the fruit and the irrigation water.

Pesticides are generally mixed with potable or drinking-quality water and sprayed directly onto the plants or the soil below. This is the only water other than rain that intentionally contacts the berries directly.

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[1] See Exhibit No. 2 which appears in the Appendix on page 45.

[2] Photograph 1 of Exhibit No. 2 appears in the Appendix on page 46.

The berries are harvested dry and not washed at any point prior to sale, because they are very susceptible to mold. Water is also a possible source of contamination. Therefore, the quality of any water that contacts the berries is significant.

Raspberries are harvested by hand, primarily by women. The berries must be handled very gently to preserve their quality. Ripe berries can be pulled from the plant very easily. The pickers generally carry plastic trays strapped around their waists to keep their hands free, as shown in this photograph.[1] The plastic trays hold small plastic baskets into which the berries are placed. Again, let me emphasize that anything that comes in direct contact with the fruit, if contaminated itself, is a possible source of contamination.

Once the baskets are full, the tray is taken to a packing shelter such as the one shown in this photograph.[2] Typically, these structures have poured concrete floors and screened pass-through windows. By passing the trays brought from the fields through a window, tracking dirt from the field into the packing shelter is avoided. Some farms also use foot baths just outside the packing shelter door to clean shoe bottoms before entering.

Inside the packing shelter, berries are classified as export grade or domestic grade based on color and degree of ripeness. The berries are generally sorted and classified on large tables with smooth white surfaces, under a covered fluorescent light as shown in this photograph.[3]

The next photograph shows workers actually sorting, classifying and packing raspberries selected for export as fresh product in plastic containers called clamshells.[4] Containers of this type are commonly used for raspberries and blueberries. The clamshells are packed in cardboard flats, as shown in this photograph.[5]

A flat holds 12 clamshells. The packaged fresh berries are stored in refrigerated rooms on individual farms or are transported within hours to exporter warehouses for cold storage prior to export. Possible sources of contamination during sorting and packing include dirty hands and tabletops.

For shipping, the cardboard flats are packed in 3'x3'x4' styrofoam-insulated cardboard boxes referred to as E-containers. One E-container holds 10 flats plus gelpacks added to keep the berries cold. The E-containers are transported in refrigerated trucks from exporter warehouses to the airport. Generally, the trucks arrive at the airport between 11 p.m. and midnight.

Upon arrival, the berries are held in cold storage in the cargo area. Between 2 a.m. and 4 a.m., the berries are loaded onto either a cargo or passenger plane. All fresh raspberries from Guatemala are shipped by air to the United States.

Miami, Florida has been the principal port of entry for fresh Guatemalan raspberries, with the majority of the berries passing through its airport. After arriving in Miami, the berries are unloaded from the planes, as shown in this photograph.[1] The berries must then be cleared by the USDA's Animal and Plant Health Inspection Service, or APHIS.

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[1] Photograph 2 of Exhibit No. 2 appears in the Appendix on page 47.
[2] Photograph 3 of Exhibit No. 2 appears in the Appendix on page 48.
[3] Photograph 4 of Exhibit No. 2 appears in the Appendix on page 49.
[4] Photograph 5 of Exhibit No. 2 appears in the Appendix on page 50.
[5] Photograph 6 of Exhibit No. 2 appears in the Appendix on page 51.

The inspectors use USDA cargo clearance areas containing examination tables for visual inspection of incoming plants and plant products, including fruit and vegetables. The role of APHIS is to protect U.S. animals and plants from the spread of foreign animal and plant pests and diseases—not to protect U.S. consumers from human disease.

For raspberries, the inspectors remove a clamshell from a flat, open it, empty the berries onto the table and visually inspect them. The berries are then returned to the clamshell, replaced in the flat, and returned to the storage location before being collected by the importers.

Removing the fruit from its container creates an opportunity for it to become contaminated by contact with human hands or with soil which may remain on the inspection table from previous examinations of plants or flowers. However, while microbial contamination could hypothetically occur in this manner, the sheer number of event locations, shippers, distributors and cargo clearance areas made the possibility of raspberry contamination occurring in the United States highly unlikely.

The FDA is also responsible for clearing imported fruit and vegetables as well as all other imported foods, except for meat, poultry and some egg products—which are under the jurisdiction of the USDA's Food Safety and Inspection Service. FDA inspectors may automatically release the fruit based on the product's import history, or the inspectors may conduct a physical examination of the fruit and/or collect a sample for laboratory testing prior to releasing the product into U.S. commerce.

Once the raspberries have been cleared at the port of entry, importers ship the berries to distributors either by airplane or by truck. Generally, if they are shipped in a refrigerated truck, the flats are stacked on a pallet without using gelpacks. If they are transported in an airplane or a nonrefrigerated truck, they are repacked into E-containers with gelpacks.

Distributors fill and deliver orders for fresh raspberries placed by retail outlets and food service establishments. Surprisingly, our investigation revealed that raspberries harvested one afternoon on a Guatemalan berry farm can be on an American consumer's table the very next day. The entire farm-to-table process can be completed in less than 24 hours, even when the farm is located in Central America.

Finally, upon receipt by the retailer or food service establishment, fresh berries are generally stored briefly until displayed for sale or prepared for consumption. Food preparation is always a potential point of contamination, depending largely on how the food is handled. That is why proper handling practices are so important. Proper food preparation practices include washing hands often, separating washed and cooked foods from unwashed and raw foods, as well as animal products from plant products.

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[1] Photograph 7 of Exhibit No. 2 appears in the Appendix on page 52.

However, as I stated previously, in these cases, it is most likely the raspberries were already contaminated prior to reaching the retailer or food service establishment.

In closing, I would like to quote one of my colleagues from the CDC, Dr. Morris Potter, who I believe accurately summarizes the challenge posed by foodborne illness: "If one recognizes that ensuring food safety is inherently uncertain, foodborne illnesses become opportunities to learn rather than failures to predict. Foodborne disease will occur, and we must be prepared to react quickly to reduce the risk of new foodborne hazards."

Further, I would like to emphasize that we live in a Nation that trades food on a global basis. In efforts to ensure the safest U.S. food supply possible from farm to table, it is essential to remember that increasingly, the farm is in another country.

In 1996, the United States imported $7.2 billion worth of fruit and vegetables from at least 90 different countries, an increase of 48 percent from 1990. And this trend will continue.

The FDA has projected that imports of fruit and vegetables will go up by another 33 percent between now and the year 2002. The United States will continue to import foreign produce to meet the demand of American consumers for a variety of fresh fruit and vegetables year round. Therefore, food safety is an international issue.

Thank you again, Madam Chairman, for the opportunity to present this phase of the Subcommittee's food safety investigation. I am, of course, available to answer questions.

Senator COLLINS. Thank you, Dr. Smith.

Dr. Foran.

TESTIMONY OF DR. JEFFERY A. FORAN,[1] CYCLOSPORA CASE PATIENT, AND EXECUTIVE DIRECTOR, RISK SCIENCE INSTITUTE, INTERNATIONAL LIFE SCIENCE INSTITUTE

Dr. FORAN. Thank you, Senator.

I am Dr. Jeffery Foran. I am Executive Director of the International Life Science Institute (ILSI), Risk Science Institute here in Washington, DC. The ILSI Risk Science Institute is a nonprofit institute established in 1985 to advance and improve the scientific basis for ecological and human health risk assessment. RSI works toward this goal through an international program of research, working groups, conferences, workshops, publications, seminars and training programs.

We recognize that public health decisions must be based on the best available science and thus, in all of our activities, we work toward consensus resolution on the scientific issues by facilitating discussion and cooperation among scientists from academia, industry, government, and the public-interest sector.

During the spring of 1996, I attended a buffet luncheon at which a variety of fruit and other foods was served. Approximately 10 days to 2 weeks after the luncheon, I developed acute gastroenteritis and diarrhea. Several other individuals who participated in the luncheon developed similar symptoms, which included nausea, fatigue, loss of appetite and weight loss.

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[1] The prepared statement of Dr. Foran appears in the Appendix on page 161.

Upon the discovery of the similarity of our symptoms, and suspecting a similar disease etiology, we contacted the Washington, D.C. Public Health Commission, and subsequently, the Centers for Disease Control and Prevention. We asked them to investigate the potential for food-related causes of these symptoms.

During the investigation of the nature of these symptoms, I visited my physician to determine what might be causing my illness. My physician did not at the time suspect a foodborne illness. Rather, he suggested that my fatigue and weight loss might be due to stress and a very hectic schedule. No medication was prescribed during my first visit.

After this visit, we began to learn through the news media of a foodborne pathogen, *Cyclospora*, which elicited symptoms in exposed individuals that were identical to my own, and others who participated in the luncheon.

I recontacted my physician upon learning of the symptoms caused by *Cyclospora* infection and the appropriate treatment. The CDC subsequently confirmed the outbreak of cyclosporiasis in individuals who attended our luncheon. I then received medication and was relatively free of symptoms within 14 days of receiving medication. Subsequently, we learned from the CDC investigation that *Cyclospora* most likely occurred on the raspberries that were served during the luncheon, and that these raspberries were most likely imported to the United States.

For several years, the ILSI Risk Science Institute has been developing a method to assess the human health risks associated with exposure to food- and waterborne pathogens. The disease outbreak in individuals who attended the luncheon has provided valuable, although I admit somewhat uncomfortable, personal lesson of the value of our work. In 1996, RSI published an article entitled "A Conceptual Framework to Assess the Risks of Human Disease Following Exposure to Pathogens."[1] This framework, which was developed by a group of 30 scientists convened by the ILSI Risk Science Institute, highlights the information that must be gathered to fully understand the health risks posed by exposure to food and waterborne pathogens. Critical to such an assessment is information on the nature of the pathogen itself—for example, where it occurs, its life-cycle, its ability to cause disease; the nature of exposure to the pathogen—how, when and how much we might be exposed to it; information on host susceptibility, the health effects caused by the pathogen, the severity of the disease in the host, the nature of the dose/infectivity/response relationship between the pathogen and the host, and an array of other factors.

Unfortunately, much of this information is not available for many pathogens that infect humans and cause diseases. For example, with regard to *Cyclospora*, at the time of our outbreak, most physicians and public health experts did not fully understand the nature of the organism, its occurrence, its infectivity, and many other issues necessary to characterize the human health risks associated with exposure to the organism. And even after significant investigation, scientists have still not resolved several of the critical issues about *Cyclospora* as well as many other pathogens, such as the nature of the dose/infectivity/response relationship, which is a key issue in conducting a quantitative risk assessment.

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[1] See Exhibit No. 8, Attachment G which appears in the Appendix on page 142.

Stated in a simpler fashion, we did not at the time of our outbreak and still do not know how many contaminated raspberries one must eat to become infected, or what concentration of *Cyclospora* oocysts must occur on a single raspberry to result in infection.

Clearly, the state of the science is poorly-advanced an likely incapable of supporting a comprehensive and conclusive risk assessment for *Cyclospora*.

Similar uncertainties confront the risk assessment community with respect to many other food- and waterborne pathogens.

Now, why is risk assessment for pathogens so important? Risk assessment is a process that facilitates the organization of information on health risks posed by exposure to pathogens. Organization of information on health risks is necessary because of the complexity of such information and the likelihood that without such an organizational process, critical pieces of information leading to an understanding of the health risks will be missed.

Additionally, the use of risk assessment methods to gather and organize information on health risks facilitates the identification of knowledge and data gaps that must be filled to fully understand and characterize risks.

Finally, and I think most important, quantitative risk assessment can provide a probabilistic expression of health risks. This information is critical in assessing the efficacy of control technologies, in comparing the benefits of different control technologies, in the conduct of cost/benefit analyses, and in facilitating the development and selection of policy options to manage health risks. Without a quantitative assessment of health risks, we are left with simple guesses as to which control technologies or policies are most appropriate to reduce health risks associated with exposure to food- and waterborne pathogens.

Risk assessment is not a panacea. It will not prevent all human infection and disease. And without reliable data, or used improperly, it can even provide misleading information. However, when used correctly and conducted with reliable data, risk assessment will provide and encourage the development of information that will lead to informed decisionmaking. It can also provide predictions of potential health risks, which can then be managed before disease occurs in human populations. At its best, it could even play a role in preventing the outbreak of cyclosporiasis and other pathogen-related diseases.

For this reason, adequate resources must be made available to conduct comprehensive risk assessments for food- and waterborne pathogens and to address the many uncertainties and knowledge gaps that accompany the risk assessment process.

I appreciate the opportunity to present these remarks and will be glad to entertain questions.

Senator COLLINS. Thank you very much.

Dr. Ostroff, it is my understanding that you are going to be presenting for the CDC today.

Dr. OSTROFF. That is correct, Senator.

Senator COLLINS. Please proceed.

TESTIMONY OF DR. STEPHEN M. OSTROFF,[1] ASSOCIATE DIRECTOR FOR EPIDEMIOLOGIC SCIENCE, NATIONAL CENTER FOR INFECTIOUS DISEASES, CENTERS FOR DISEASE CONTROL AND PREVENTION, ATLANTA, GEORGIA, ACCOMPANIED BY DR. BARBARA L. HERWALDT, MEDICAL EPIDEMIOLOGIST, DIVISION OF PARASITIC DISEASES

Dr. OSTROFF. Let me begin by thanking you and other Members of the Subcommittee for holding this hearing and for your ongoing support and interest in food safety.

As mentioned, I am the Associate Director for Epidemiologic Science at the National Center for Infectious Diseases, and thus, I am responsible for all of the outbreak investigations that we do. I am accompanied by Dr. Barbara Herwaldt, from the Division of Parasitic Diseases, who coordinated our investigations of *Cyclospora* in 1996 and 1997.

This is a dynamic period for public health and infectious diseases. Almost every year, we find a new disease-causing microbe or discover the causative agent for a previously-known disease, including ones like HIV, *E. coli O157:H7*, hepatitis C and hantavirus.

Today, there are many challenges in our ability to protect the public's health. These include changing technologies, changes in the environment, global movements of people and products, population growth, and social and behavioral changes. These factors certainly operate in the area of food safety and foodborne diseases, where forces which were hard to imagine at the turn of the century, play a major role today, including a globalized food supply, large-scale food production and distribution networks, and changes in consumer eating habits.

Although Americans have one of the safest and most diverse food supplies in the world, foodborne diseases remain a threat to us all. It has been estimated that between 6 and 33 million foodborne illnesses occur each year in this country. As a result of evolving patterns of food supply and production, the spectrum of foodborne disease is also evolving with new agents and patterns of transmission occurring.

CDC's mission, put very simply, is to keep our finger on the pulse of the public's health. In the food safety area, we work with a variety of public and private partners to conduct surveillance for foodborne illness, investigate outbreaks, and perform special epidemiologic and laboratory studies.

In public health, surveillance means the ongoing collection of information about health events such as cases of salmonellosis or botulism. Traditionally, this has been done using a system set up at the turn of the 20th Century in which physicians, hospitals and other sources reported illnesses to the health department. Today, these systems are simply not adequate by themselves to address 21st Century foodborne disease problems.

In 1994, we issued a strategic plan called "Addressing Emerging Infectious Diseases: A Prevention Strategy for the United States,"[1] which emphasized harnessing modern communications, computing and molecular biology to conduct our surveillance, applied research and prevention mission. This has been the platform for all of our activities under the President's National Food Safety Initiative.

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[1] The prepared statement of Dr. Ostroff appears in the Appendix on page 165.

[1] Exhibit No. 3b is retained in the files of the Permanent Subcommittee on Investigations.

It seems natural to ask why the estimates of the burden of foodborne disease are so rough. In order to determine the true burden, a series of actions have to occur, as you will see on the poster that is about to be displayed.

First, the illness must be serious enough for the victim to seek medical attention. Then, the clinician must consider the cause to be foodborne and request the proper tests. The right specimens have to be collected, and the lab must be able to do the right tests. The results must then be reported to the health department and eventually to CDC.

For many cases, not all of these steps occur, and these cases are missed. As an example, we estimate that there are 2 million cases of salmonella infection in the United States annually, but only about one in 40 are ever identified and reported to the health department.

CDC and its partners have been working to build better reporting of foodborne illnesses. These steps include building better capacity in State and local health departments for foodborne disease investigation and lab diagnostics, establishing automated reporting systems for foodborne pathogens, and, for better and faster analysis of data, creation of a system known as FoodNet in seven health departments around the country to actively seek out cases of foodborne illness and determine the true burden of diarrheal disease. FoodNet is one of the major tools we must have to demonstrate the impact of actions initiated by our partners at USDA and FDA, such as the 1997 Food Code and HACCP measures, on the ultimate goal of lowering the incidence of human foodborne diseases.

Outbreaks are defined as a greater number of cases of illness than expected within a given time frame or geographic area. About 400 to 500 foodborne outbreaks are reported annually to CDC. This, too, is likely to be a gross underestimate as many outbreaks are never recognized, and seemingly sporadic cases of illness are never linked together.

To better identify outbreaks, CDC has worked to create the PulseNet system for molecular fingerprinting of foodborne pathogens, much like the local police department fingerprints criminals.[2] This poster shows the current status of the FoodNet system, which is nationally based, with a centralized computer database at CDC.[3] Whenever we find two microbes with the same fingerprint pattern, it means they are somehow linked. Our job is to find out how.

Using resources provided by CDC, routine use of this technology allowed Colorado to recognize the *E. coli* outbreak linked to beef patties last year, leading to the recall of 25 million pounds of ground beef. This outbreak surely otherwise would have been missed.

Molecular viral sequencing allowed us to show that the cases of hepatitis among schoolchildren in your home State of Maine last year were part of the larger frozen strawberry outbreak which was mentioned by Senator Levin in Michigan school children at the same time.

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[2] See Exhibit No. 5a which appears in the Appendix on page 55.

[3] See Exhibit No. 5b which appears in the Appendix on page 56.

CDC's role in outbreak investigations is very well-illustrated by the 1996 and 1997 outbreaks of infection caused by *Cyclospora*, which the other two presenters have mentioned.

Senator COLLINS. Excuse me, Doctor, I apologize for having to interrupt you. We are in the midst of a vote, and I have only 2 minutes to make it to the floor.

It seems to me this is a good breaking point, because I know the next part of your testimony will talk specifically about the 1996–1997 outbreak of *Cyclospora* which is our cases study today.

Dr. OSTROFF. That is correct.

Senator COLLINS. So, with apologies to everyone, I am going to call a 15-minute recess, because we unfortunately have two votes. I hope I will make this one, and then we will have a second vote, and I will come back as soon as possible.

We will be in recess for 15 minutes. Thank you.

[Recess.]

The Subcommittee will please return to order. Dr. Ostroff, I will ask you to continue with your excellent testimony.

Dr. OSTROFF. Thank you, Senator.

Getting to the *Cyclospora* issue, CDC's role in the outbreak investigation is very well-illustrated by the outbreaks of infection caused by *Cyclospora* in 1996 and 1997. *Cyclospora* is typically characterized by watery diarrhea and other symptoms such as nausea, abdominal cramps, weight loss and fatigue. If not treated, as was mentioned, the illness can be severe and prolonged.

Before 1996, most of the small number of cases of cyclosporiasis in the United States occurred in travelers who had been in developing countries, and only three small U.S. outbreaks had been reported.

This pattern changed dramatically in 1996 when health departments noted cases of cyclosporiasis in people who had not traveled overseas. In mid–May of 1996, health departments in Florida and New York informed CDC that sporadic cases of cyclosporiasis had been identified in their States. At the end of May, health departments in Texas and Canada told us that some people who had attended specific events such as a party had become ill with cyclosporiasis. Thus, we were notified of what we refer to as "clusters" of cases, which indicated that an outbreak may be occurring.

Ultimately, 55 clusters with a total of 725 cases of cyclosporiasis were reported to CDC by 14 States, the District of Columbia and two Canadian provinces. These clusters were associated with events that had occurred between May 3 and June 14, 1996. In addition, 740 sporadic cases that were not associated with identified events or with overseas travel were reported, for an overall total of almost 1,500 cases from 20 States, District of Columbia, and two provinces in Canada.

Twenty-two people are known to have been hospitalized, but no deaths are known to have occurred. As mentioned earlier, because many cases are probably not recognized, these numbers are likely to be very gross underestimates.

CDC played many roles in the outbreak investigation, including serving as the national reference laboratory for identifying

Cyclospora in stool specimens, thus confirming that the parasite caused the outbreak. This role was particularly important because many laboratorians had not had any experience in identifying *Cyclospora*.

We also helped State and local health departments conduct the studies that ultimately implicated raspberries as the food item that had made people sick, focusing on the clusters of cases that were associated with specific events. Health departments interviewed the people who had attended the respective events about what they had consumed and compared the responses of the sick and the well people to see how they differed. CDC assisted in various ways—for example, by helping to design the questionnaires, conduct the data analysis, and identify important issues that needed to be addressed in the investigations. In several instances, we actually fielded teams to assist the State health departments with the investigations.

As more and more clusters of cases were identified, CDC's coordinating role at the national level became more important. We sponsored frequent conference calls for all participants who were doing investigations and a meeting in July 1996 to discuss the findings to date and help establish priorities for the investigation and for future research.

Whereas the investigators from the individual States and localities were able to focus on their own jurisdictions, our job was to look at the overall national patterns that emerged as data from the individual clusters was compiled and analyzed.

Fresh raspberries were found to have been served at virtually all of the clusters of events, and a strong statistical association was found between illness and consumption of raspberries. Studies that compared the exposures of sporadic cases and control subjects were also conducted and also implicated raspberries.

Once it was determined that raspberries were the food item responsible for illness, the next step was to determine where they had been grown, a process which required close coordination with FDA, State and local agencies, and industry. The tracebacks entailed determining where the various events took place and where the raspberries that were served had been bought. The raspberries were then tracked from suppliers and distributors back to importers, exporters and farms of origin, looking for common themes at each step. The available traceback data implicated Guatemala as the common source for the raspberries.

Investigators next tried to determine how the raspberries became contaminated. We sent investigators to Guatemala and Miami, a major port of entry for imported raspberries, to explore possible modes of contamination. We were able to observe how raspberries were grown, picked, sorted, packed, cooled, transported and inspected. Because no step along the path after the berries left the farm was linked to all events for which we had adequate data about the source of the implicated raspberries, we concluded that some practice or attribute common to multiple farms was the most likely explanation for the outbreak.

As was mentioned, one hypothesis was that contaminated water may have been used to mix the insecticides, fungicides and fertilizers that were sprayed on the raspberries. Good laboratory methods for detecting low levels of the parasite on produce such as raspberries, or in water and other environmental samples, are not available. By the time the clusters of cases were detected, leftover raspberries from the events were not available for testing.

Although the precise mechanism by which the raspberries became contaminated was unclear, FDA and CDC provided suggestions to the Guatemalan Berry Commission about possible ways to reduce the risk for contamination. The Berry Commission voluntary implemented various prudent measures to improve water quality and sanitary conditions on farms that were going to export to the United States in subsequent export seasons.

Despite these control measures, another multi–State outbreak linked to Guatemalan raspberries occurred in North America in the spring of 1997. CDC learned of this outbreak in early May 1997, when several health departments informed us of clusters of cases that were associated with April events. Ultimately, 41 clusters with over 700 cases were reported which were associated with events that occurred April 1 through May 26, 1997, in 13 States, the District of Columbia, and one Canadian province. Counting the sporadic cases, more than 1,000 cases in 17 States, District of Columbia and two provinces were identified.

Once again, the investigation which focused on the clusters of cases implicated fresh raspberries and Guatemala was found to be the major source of the implicated berries. The outbreak ended shortly after Guatemala voluntarily suspended exportation of fresh raspberries to the United States at the end of May 1997.

Why did the second outbreak occur? One possibility is that the control measures on the farms were never adequately implemented. Another is that the true source of contamination was not found, so that the measures which were taken did not control the problem. The latter is certainly possible since there are so many critical questions about this parasite which we cannot answer.

For instance, we do not know where the parasite lives in nature. With no animal models for the disease, it cannot be easily studied in the laboratory setting. Infected human stool is the only source we have for this parasite, so a ready supply of the organism is not very easy to obtain. We have no test to tell us whether the parasite is alive or dead, other than when it causes human illness, and no subtyping methods like we do for some of our other pathogens. Most importantly, we do not have a good test for it in fruit or in water.

Although this parasite can be cured with antibiotics, as our mothers told us, an ounce of prevention is worth a pound of cure. Lacking these answers, the only preventive measure available to FDA was to restrict the import of Guatemalan raspberries into the United States between March 15 and August 15 of this year. So far, this step seems to have worked, since we have seen no *Cyclospora* outbreaks linked to raspberries in the United States this year.

The *Cyclospora* story is a model for emerging foodborne diseases in many ways. This includes a newly-recognized pathogen, many unanswered scientific questions, an unusual food vehicle for disease, a high-profile disease outbreak involving thousands of people over multiple States and countries, and economic and diplomatic overtones.

As we move into the next century, we are likely to see more stories like *Cyclospora* that involve a newly-recognized microbe and many unanswered questions. We must have the tools at hand to rapidly recognize and respond to these new foodborne threats. As we work toward this goal, the number of reported cases and outbreaks will probably first go up rather than down. This should be viewed as good, as it means we will be seeing the problems that we now surely miss. We can only devise appropriate preventive measures and assure ourselves that our risk reduction strategies work if we know what the problem are that are out there. We owe this to you and to the American consumer as we move into the next century.

Thank you for your time, and both Dr. Herwaldt and I would be happy to answer any of your questions.

Senator COLLINS. Thank you very much, Dr. Ostroff.

Dr. Ostroff, let me start by asking you a question about the recent outbreak of *Cyclospora* in Canada. You mentioned just now that the United States took steps to ban the export of Guatemalan raspberries, which seems to have prevented the spring outbreak in the United States that occurred during 1996 and 1997. In Canada, however, we have had a spring outbreak of *Cyclospora* just this year. Can you tell us anything about the Canadian outbreak? Is CDC involved at all in assisting the Canadian public health authorities in trying to do the traceback process?

Dr. OSTROFF. Yes. Let me answer very briefly and then I will ask Dr. Herwaldt if she has anything to add.

We have been assisting the Canadians in looking into the outbreaks, the clusters, which have been recognized so far in 1998. Our understanding is that there have been 14 separate clusters that have been recognized involving about 200 individuals. Certainly the preliminary data—and those numbers will probably change; they are very preliminary—suggests that these outbreaks are once again linked to raspberries. The preliminary information in terms of the tracebacks suggest that the source was Guatemala.

Again, we have been assisting the Canadians in terms of conducting the investigations as well as the tracebacks.

Barbara, do you have anything to add?

Dr. HERWALDT. No. I would just like to reiterate what Dr. Ostroff said. The investigation is ongoing. All the numbers are preliminary. Both clusters and sporadic cases have been identified, and as he pointed out, both the epidemiologic and traceback investigations to date are leading us and the Canadians to the conclusion that again, Guatemalan raspberries have caused this outbreak.

Senator COLLINS. Dr. Herwaldt, I would like to examine with you in more detail the traceback process. Senator Lieberman aptly described it as being akin to a medical detective story, and I think it is, in many ways.

I know that the CDC is not responsible for every part of the investigation, but I would like you to respond based on your knowledge of how other entities cooperate with the CDC and give us a fuller picture of the traceback process going from a patient like Dr.

Foran, who became ill from eating the contaminated raspberries, back to the farms in Guatemala.

First of all, I assume that you start with reports from State health departments that identify an incidence of cyclosporiasis and that they were greater than normal. But it must have been difficult for public health authorities, given what Dr. Ostroff has told us about the lack of information and the lack of tests, to deal with this rather exotic microbe that we are dealing with in *Cyclospora*.

Could you tell us how the reports came to the CDC and walk us through the process?

Dr. HERWALDT. Yes. Thank you for the question.

These sorts of investigations are very complex, as you alluded to, and difficult to conduct. It requires the collaborative work of many persons from many agencies. As you said, we initially hear about cases of ill persons from State health departments, local health departments, sometimes from the physician and sometimes from the patient himself or herself.

Cyclospora is one of the many emerging pathogens that we are dealing with, and many people in State and local health departments know that we are interested in organisms such as *Cyclospora* and do let us know when they hear of cases.

As has been previously mentioned, there are some severe constraints we are operating under because many sick people may not go to see their doctors, and many doctors may not do the appropriate tests. They may not realize that you have to specifically request testing for *Cyclospora* to have the testing done. Many laboratories, at least before the 1996 outbreak, did not yet have the necessary experience and expertise to identify the organism even if they did the appropriate test.

So there were many links along the chain for us to even hear that a case was caused by *Cyclospora*. Sorry, did you have a question?

Senator COLLINS. Once you do get that report, is there an interview process where you try to figure out who ate what, at what event?

Dr. HERWALDT. Exactly.

Senator COLLINS. I mean, to try to identify the food involved must be a difficult task and involve some sort of interview process; is that correct?

Dr. HERWALDT. Yes.

Senator COLLINS. Tell us about that part of the process.

Dr. HERWALDT. OK. We have two types of cases, and I will emphasize what happened with the clusters of cases. These were associated with events, or parties. To investigate them, the health department would use a structured questionnaire and interview both sick people and well people, asking them not only about their symptoms, but about everything they ate and drank at the event. Then they would compare the exposures of the sick people and the well people to see how they differed. Then, statistical tests would be used to determine what could differentiate the exposures and determine what caused the illness.

We had both the blessing and the curse of having multiple clusters. We did not have just one little one; we had multiple ones. It was both a blessing and a curse. It was a curse because, obviously, it required much more work, but it was a real blessing because it strengthened our conclusions and made them all the more compelling because we had the same conclusions being reached by multiple investigators scattered all across the country and also in Canada.

Senator COLLINS. When did it become evident that the raspberries were the culprit?

Dr. HERWALDT. Well, there are a couple of different kinds of evidence. First and foremost, the mere fact that raspberries overwhelmingly were the common theme was an important observation. Of course, that was not clear at the very beginning because we just knew of a few clusters at that time. But as we heard of more and more clusters and more and more events and learned about the menus, it became quite obvious that raspberries were the common theme.

Then, we moved one step beyond that. We did not rely on that alone. We also wanted strong statistical evidence that could compellingly say with real confidence that it was the raspberries.

Senator COLLINS. Once you identified raspberries as the source, how did you then go about determining where the raspberries came from?

Dr. HERWALDT. In all aspects of the investigation, we looked for common themes. That was true for the epidemiologic aspects, and it was true as well for the traceback aspects. We looked for common themes at every step along the way.

To trace the source of the raspberries, we had to, as Dr. Smith pointed out, look at every step. We were going in reverse; it was to trace back from the table back to the farm. For example, if there was a party, we needed to find out where the raspberries were bought, where they came from—was it a restaurant, was it a supermarket—where that supermarket or restaurant got its raspberries. We had to go back to the distributors, and from the distributors back to the importers, and from the importers back to the exporters, and from the exporters back to the farms.

So every step along the way had to be investigated in detail, and again, the overwhelming common theme was Guatemala, so that we could confidently conclude that not only were raspberries the vehicle but that Guatemala was the source of the raspberries.

Senator COLLINS. Did the CDC actually visit farms in Guatemala to try to pinpoint the source of the contamination?

Dr. HERWALDT. Yes. CDC in fact fortuitously has a field station in Guatemala which has facilitated our investigation, but on multiple occasions, officials from CDC here in the States, as well as from FDA and other agencies, have gone to Guatemala. Unfortunately, we have not been able to identify with confidence the mode of contamination. As has been previously mentioned, we have various hypotheses, but we do not yet know with certainty what caused the problem.

Senator COLLINS. The CDC was able to trace the source back to specific farms. As I understand it, there were 10 farms that were visited, and your statistical analysis suggests that five farms could have been the source of some 85 percent of the contamination. Is that accurate?

Dr. HERWALDT. That is actually a little bit complex, because the problem is you do not always know with certainty which shipment of raspberries was used to supply a supermarket or a restaurant or whatever. Then, in addition, usually, multiple farms contribute raspberries to a shipment of raspberries. So what we needed to do was say for an individual event, this was the list of possible farms that could have contributed the raspberries, and then we again looked for common themes. We were able to say the minimum number of farms that could have been responsible, but we did not know for sure necessarily that it was Farm X, Farm Y, Farm Z, in all cases. But we can say that no one farm could have accounted for the whole outbreak, nor could any one exporter have accounted for the whole outbreak, and that is true for the 1996 outbreak and the 1997 outbreak.

Senator COLLINS. Is the CDC's best hypothesis at this point that it is a case of contaminated water used by the farms?

Dr. HERWALDT. I would say that that is one of our major hypotheses, and it is an attractive hypothesis for several reasons. First and foremost, we know that this organism can be transmitted by the waterborne route. Also, another reason the hypothesis is attractive is we need a hypothesis that can account for the fact that both outbreaks were rather long, and no one farm could account for the entire outbreak. So we needed a mechanism for contamination of relatively large numbers of raspberries.

But given that it is an emerging pathogen, so many unanswered questions, and we do not have definitive evidence of how the contamination occurred, we do not want to be too strong in what we say about how it might have occurred.

Senator COLLINS. Thank you.

Dr. Smith, I would like to turn to you to learn more about the Subcommittee's investigation and specifically, your visit to the 10 berry farms in Guatemala.

First, are raspberries native to Guatemala?

Dr. SMITH. They are not.

Senator COLLINS. Could you tell us how raspberries came to be grown in Guatemala and the role that the United States may have played in that effort?

Dr. SMITH. Actually, it was the United States Agency for International Development that, through contractors, got the Guatemalans and other Central American countries into nontraditional agricultural crops for export.

In the 1980's, the contractors introduced blackberries, and then the decision was made, because of the demand being higher in the United States for raspberries, that raspberries be considered, and in fact, in the early 1990's raspberries were introduced.

Senator COLLINS. Could you tell us a bit more about your observations on the farms that you visited? Did they vary as far as the conditions you found on the farms, or were they all approximately the same? Tell us more about your personal observations as a food scientist when you were in Guatemala.

Dr. SMITH. Actually, at the time we were there, which was the end of March, beginning of April of this year—and some things have changed since then as far as measures put in place—but at the time, they were categorizing based on a set of criteria, and they had inspectors give scores. The criteria included water source, the packing shelter, materials that were used to make the structure itself, recordkeeping, personal hygiene of employees. These kind of things were considered, a numerical value was given, and then, based on that numerical value, the farms were categorized high, medium or low risk.

Since then, the high-risk farms have gone out of business, and I believe even since then, some of the medium-risk——

Senator COLLINS. Excuse me. Since your visit, some of the high-risk farms where you observed conditions that caused you concern are now no longer in production; is that correct?

Dr. SMITH. Actually, we did not even go to a high-risk farm. We saw a medium-risk farm, and medium-risk farms are now out of business, too.

So when AID first went down, there were about 12 farms that they worked with, and that grew to about 150 farms, and the most recent information I have is that they are back to about 26 farms. So that only the farms doing the best job with the best infrastructure are still remaining and being considered for potentially exporting to the United States next spring.

Senator COLLINS. Understanding that the farms that you observed may no longer be producing, could you describe some of the conditions that caused you concern and that could be a possible source of cyclosporic contamination?

Dr. SMITH. Yes, and I will refer to notes that I took while in that country. We did see one medium-risk farm, and one concern that I had was dirty toilet facilities. Actually, when I went to wash my hands after using the facility, I could not get water out of it; but I was shown to a sink inside which the employees were using, and there was water with soap and paper towels. Again, that was a medium-risk farm and is no longer in existence.

Senator COLLINS. Dr. Foran, one of the most fascinating aspects of your testimony was that when you became ill, you went to your physician, and your physician was not able to diagnose you originally as having a foodborne illness. It sounds to me like you more or less put the evidence together yourself when you heard of your friends who were at the same luncheon, who also had similar symptoms.

In addition, I believe that you read about press reports of *Cyclospora*. Is that accurate?

Dr. FORAN. Yes. The group of us that participated in the luncheon all developed the same symptoms, identical symptoms, at the same time. As a scientist, but even as an individual, that was well beyond any expectations of coincidence.

That led to the first suspicion, although we did not know the disease or what was causing the symptoms. But shortly after that, we saw an article in *The New York Times* that described an outbreak of cyclosporiasis, I believe it was in New York, and it described the symptoms associated with that outbreak, and they were identical to our own. At that point, simply putting two and two together was very easy.

Senator COLLINS. Dr. Ostroff, that suggests that public disclosure of foodborne illnesses is very important, because in this case, it enabled Dr. Foran to get treatment that he might not otherwise have gotten. And while it is my understanding that people do not die of cyclosporiasis, there are other foodborne pathogens that can cause death.

How does the CDC decide when it has enough evidence of a foodborne illness to make that information public and thus to alert unsuspecting clinicians or patients that they may in fact be suffering from a foodborne illness?

Dr. OSTROFF. Senator Collins, that is an excellent question, and it is an issue that we constantly struggle with as we conduct investigations with our partners at the State and local levels of foodborne disease outbreaks.

A similar example in the last couple of months has been the salmonella outbreak in the Midwestern States which turned out to be associated with the toasted oats cereal.

Part of the difficulty is that if you make an announcement before you have all the data you need to assure yourself with scientific certainty that you are correct, you could potentially implicate the wrong product, that would put a smear on a product and an industry that you will have difficulty dealing with. In addition, it will not be preventing any illness.

Alternatively, if you wait too long, you decrease the likelihood that you are going to be able to prevent additional cases of disease.

In addition, certainly at the Federal level and at the State level and at the local level, there are very different priorities in terms of being able to get information out to the public about a perceived risk. It requires an enormous amount of coordination to be able to successfully know the precisely correct moment to inform the public about these problems.

One thing that we have done at CDC is to work very collaboratively with our partners at the State level and the Council of State and Territorial Epidemiologists to set up a group that can get together 24 hours around-the-clock to discuss all of the epidemiologic information that has been collected up to a certain point. This allows us to make a unified determination about whether we have enough to go public with the information. This is one of the things we have set up in the last year or two to specifically deal with the problem that you have identified.

Once we feel that we do have that information, we make the full court press to the degree that we can to get this information out, both in terms of presenting the information to the media, putting reports in our weekly report, which is the Morbidity and Mortality Weekly Report. With the increased scrutiny and attention that foodborne outbreaks are getting, the level of media interest has increased astronomically, so there is much more attention and much more likelihood that people will hear about these problems, but it is a very delicate issue.

Senator COLLINS. Thank you.

Senator Lieberman.

Senator LIEBERMAN. Thank you, Madam Chair. I regret that I have been in and out today, because this hearing is of real interest to me, but I did get a chance to read the testimony that was submitted beforehand, and I appreciate very much your presence here today.

Dr. Smith, I want to start with you, and again, thank you for your excellent work for the Subcommittee. In your testimony, you mention that pesticides in the Guatemalan farms are often mixed with what is described as drinking-quality water. I noticed a memo which was an attachment to the Permanent Subcommittee on Investigations' excellent report, from a Dr. Marta Ackers of CDC, which described water that does not sound very appealing, which is to say that several of the implicated farms drew from open reservoirs, shallow wells or rivers which were subject to contamination. It continues, "On at least one farm, the river from which the farm obtained its water supply was noted to have people bathing in it upstream, in addition to garbage floating in it."

And the article in *The New England Journal of Medicine* describing this outbreak refers to wells maintained near deep-pit latrines or seepage pits.

My question is is it fair to assume that the drinking water quality in Guatemala falls far below the health standards that we would apply to that term here in the United States—or, am I being unfair in taking that term "drinking-quality water"——

Dr. SMITH. I think I know what you are getting at, Senator. Certainly, even in Guatemala, I do not think they would consider that "drinking-quality" water. And what is important to keep in mind is that that report referred to the outbreak which occurred in 1996, and since that time, there have been continual efforts, and in cooperation with FDA and CDC, the Guatemalans have tried to put in place practices that are closer to what the United States does to the point now where I would say that they are very comparable. And the most recent proposal submitted by the Guatemalan Government in order to be allowed to export to the United States next spring would be that their three best farms, which FDA is requiring have filters, where the mesh is actually small enough that it would not allow the *Cyclospora* organism to get through, to be used prior to the water being used in any way associated with the plant.

Senator LIEBERMAN. So the conditions described in Dr. Acker's memo from CDC and in *The New England Journal of Medicine* article, which are certainly unappetizing and unsanitary——

Dr. SMITH. And unacceptable.

Senator LIEBERMAN [continuing]. Unacceptable—to the best of your knowledge of the circumstance now, those are being changed, or being improved.

Dr. SMITH. Correct, and that has been with assistance from the U.S. Government agencies. CDC and FDA have been providing assistance. The Guatemalans have also hired U.S. scientists as consultants to help them get proper procedures in place and improve their infrastructure.

Senator LIEBERMAN. OK. Just to show how complicated this can be, but you will help me understand it—let us assume they install the kind of very modern, elaborate filtration system for the water. How do we assure ourselves that they are guarding against surface water runoff which may bring with it contaminants—or is that less of a real concern?

Dr. SMITH. The primary concern would be water that is intentionally put on the plant. Certainly, runoff is also a concern. Part of the problem here is that we do not really understand what the source of the contamination is, and if we had a better understanding of how it was getting introduced onto the product, we could take preventive measures accordingly.

So that has been the challenge. This organism—and Dr. Herwaldt can comment more about the organism's unique characteristics—but it seems to be highly seasonal and has been associated with the rainy season.

So the more we learn about this particular organism, the more it is going to help with taking the proper preventive measures and interventions necessary.

Senator LIEBERMAN. That leads me to the next question. I was very interested in the chart and the way you tracked the raspberries from the farm in Guatemala to the stores and in a sense to the tables here in the United States. I want to go back to the port of entry when the raspberries entered. Am I correct that the U.S. Department of Agriculture does inspect the raspberries at that point?

Dr. SMITH. That is correct, APHIS.

Senator LIEBERMAN. And what is the nature of that inspection?

Dr. SMITH. That is merely a visual inspection. The inspectors actually put the fruit or vegetable out on a table and look for insects—live insects would be actionable—or signs of disease.

Senator LIEBERMAN. In the fruit itself?

Dr. SMITH. Yes, or maybe there would be a soft, brown spot.

Senator LIEBERMAN. Which again would be visibly observable?

Dr. SMITH. Correct.

Senator LIEBERMAN. And the goal there is—certainly, with the inspections, I presume the goal is to stop insects from coming in that could affect——

Dr. SMITH. U.S. crops.

Senator LIEBERMAN [continuing]. U.S. crops. And the visual inspection is for what we might call just bad fruit which would affect people who would eat it, or——

Dr. SMITH. That is the distinction I need to make, that the mission of APHIS——

Senator LIEBERMAN. Why don't you spell it out for us?

Dr. SMITH. I am sorry. It is the Animal and Plant Health Inspection Service, and that is under the Department of Agriculture. Their mission is to protect the United States plant and animal resources. So they are not looking at food for human disease, and it is incidental in some ways that plant materials are actually food. So they are looking at it as plants rather than as food.

Senator LIEBERMAN. And at the port of entry, does the FDA play any inspection role?

Dr. SMITH. The FDA does. They have to clear each entry. That may just involve looking at the paperwork that comes with the entry. It could also involve, however, visual inspection, going and looking at the product, and in addition they may decide to sample the product and have laboratory testing done.

Senator LIEBERMAN. Do you have any idea what the nature of the inspection of this particular run of Guatemalan raspberries was when it came in?

Dr. SMITH. I do not know.

Senator LIEBERMAN. But is it fair to conclude that at this point, just to make the point, our law and its implementation really does more to protect plants and animals in the United States than it does to protect people who eat the fruit or vegetables coming in?

Dr. SMITH. Certainly, APHIS looks after plant and animal health. I would not say that FDA does not look after human health, though. I think the issue here is that *Cyclospora* cannot be detected visually, and there is not even a laboratory test for it.

Senator LIEBERMAN. I want to get to that. I guess the point I want to make is that from what I understand—and it is unsettling, but it is something that I hope we will deal with—on the average, fruit and vegetables coming into the United States are much more likely, because there is a larger apparatus there to be researched, to be inspected by APHIS of the Department of Agriculture for possible damage to plants and animals in the United States, than to be inspected by FDA for possible damage to people, because FDA does not have the same resources to do it. You can almost always be sure that there was some kind of visual inspection of the fruit by the Department of Agriculture, and clearly not so by the Food and Drug Administration.

Dr. SMITH. I was told by an APHIS inspector that their target is 2 percent per shipment.

Senator LIEBERMAN. Two percent of every shipment is inspected.

Dr. SMITH. Correct.

Senator LIEBERMAN. Then, the second point that you made is an important one, and this goes to the question of how do we come up with a remedy that not only looks good, but really does something, which is that when we are talking about organisms like the one involved in cyclosporiasis, a visual inspection would not do anything; right?

Dr. SMITH. That is correct.

Senator LIEBERMAN. Let me ask the CDC, is it conceivable that we might get to a point—is there technology being developed where we might get to a point where fruit and vegetables coming into the United States could be subjected to some kind of inspection that would reveal pathogens like this one, or all the others that have caused illnesses?

Dr. OSTROFF. I guess, Senator, the easy answer to that is that at some point in the future, we may reach that point, but ultimately, the better thing would be to not have to worry about having to do the test in the first place. Certainly, especially for fruit and vegetables, if you look at the raspberry issue, raspberries are very highly perishable. That is why, in terms of the process that Dr. Smith was describing, you have to very rapidly get them from farm to table, or they have perished. To potentially have to hold them up to conduct this type of testing and receiving the results, would decrease the relevance.

Senator LIEBERMAN. So the science here is a ways away.

Dr. OSTROFF. Yes, that is correct.

Senator LIEBERMAN. And as we think about remedies for this problem to protect people from diseases carried by food imported into the United States, it may be—the discussion that Dr. Smith and I had indicated that FDA does not really have much in the way of inspection at the port of entry—that the real point here is the other one we are talking about and that you have worked on here, which is to try to establish standards in the country of origin, of growth, to raise the level to guarantee that we are going to eliminate the possibility for these diseases which really cannot be seen in an easy way. We are not even sure now exactly what caused this outbreak, are we?

Dr. OSTROFF. No. That is correct, Senator.

Senator LIEBERMAN. Madam Chair, I have a few more questions, and I can yield back to you or follow your judgment as to whether you want to do another round.

Senator COLLINS. Why don't we do one more round. I only have a few more myself.

Senator LIEBERMAN. Fine. Thank you.

Senator COLLINS. Dr. Herwaldt, I was reading one of the CDC reports which contained the intriguing information that the Guatemalan population experiences during the rainy season what I guess is called "mal de Mayo," which is a gastrointestinal disease that seems to come in the spring. Similarly, it appears that the Guatemalan raspberries that are tainted with *Cyclospora* are also seasonal. There does not seem to be a problem in the fall, the winter or the summer, but just in the spring.

Do you think there is a connection? Does that suggest that *Cyclospora* is the cause of the illness that the Guatemalans are suffering through in the spring and also could be—I am just asking. I was intrigued as I was reading through the report.

Dr. HERWALDT. We wish we could answer that question, and actually, it is probably a series of questions. It is a very intriguing thought, and it is one that we have been wrestling with since these outbreaks occurred.

The first point is an important one, which is that this does appear to be a seasonal disease, not only in Guatemala, but in some other countries where it has been studied. In Guatemala, human infection does peak during the spring months. But as we have pointed out before, we still do not know how the raspberries became contaminated, and therefore, do not know whether humans played a role in that contamination either directly or indirectly.

Certainly, "mal de Mayo" is caused by a number of different microbes, so it is not just *Cyclospora*. *Cyclospora* is part of "mal de Mayo," but it is not all of "mal de Mayo." We need to have a better understanding not only of "mal de Mayo" but of the seasonality and what accounts for it.

We can say that the 1997 outbreak actually began before the rains began in earnest, and therefore, although moisture may play a role, it is probably not as simple as saying that when the rains begin, then *Cyclospora* begins. We do not have all the answers.

Senator COLLINS. Let me ask you a question, Dr. Ostroff—I was not trying to play medical detective there, but it does strike me as an interesting coincidence that suggested a possible link. Another question that has been raised is why raspberries and why not blackberries, which are also grown in Guatemala. We have two electron photomicrographs of a raspberry and a blackberry, and as they are shown here,[1] you can see that the surfaces of the two berries appear to be very different.

Could the differences in the berries' surfaces account for why *Cyclospora* has been associated with Guatemalan raspberries but not Guatemalan blackberries? Is that something that has been looked at?

Dr. OSTROFF. I think it is certainly one hypothesis that may indeed play a role. If you look at these pictures, it is obvious that the surface of raspberries, especially when you look at them under a microscope, is quite convoluted. There are lots of crevices and lots of nooks and crannies on the raspberries. We know that some of those nooks and crannies are the exact size that makes a very nice place for an organism like *Cyclospora*, which is 8 to 10 microns in size, to hide out. That is certainly one possibility.

What we do know is that the overwhelming preponderance of the data that was collected in 1996 and 1997 certainly suggested that raspberries were the major culprit. It does not mean that we could totally exonerate blackberries, because certainly in many of these clusters, at many of these events, at many of these parties and weddings, we know that what was actually served was a fruit cup, or some item which had multiple different berries including, in some instances, blackberries.

We cannot say with absolute certainty that there has not been any illness associated with blackberries. What we can say is that the overwhelming amount of the evidence certainly suggests that raspberries were the major culprit here.

Senator COLLINS. Thank you.

Dr. Foran, could you elaborate more on the role that you think risk assessment could play in helping us get a handle on this problem of foodborne pathogens?

Dr. FORAN. I was intrigued by Senator Lieberman's question or statement at the end of his observations, which I thought were excellent, about the level of guarantee I think he suggested, and should we be able to implement a particular technology, say, in Guatemala to deal with *Cyclospora*. I would phrase that question just a little differently, that is, rather than suggest that we want to know something about the level of guarantee, we want to know something about the level of risk reduction, and that is where risk assessment comes in.

Suppose we implement technology—a filter of some sort to remove the pathogen. Well, it is unlikely that there is anything we can do that completely removes the pathogen from a process. So the consequence will be that we will have some pathogen leftover.

I think the question we have to ask is how much pathogen is left over, and how much risk does that pose when it is left over, assuming that some of those raspberries will have a small amount of pathogen left on them when they come into the country.

Again, that is where risk assessment can play a very important role. One, it can predict the risk associated with eating the raspberries when there is a small amount of pathogen left on them, so it can help us understand the efficacy of the technology that we use to reduce pathogen.

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[1] See Exhibit No. 4 which appears in the Appendix on page 53.

Two—and what is more likely with regard to *Cyclospora*—it is going to tell us that we do not know what the answer is, and we do not know what the answer is because there is a whole array of uncertainties—we do not understand the dose/infectivity/response relationship; we do not even understand how to detect the organism.

I argue that risk assessment is a very effective tool in organizing and identifying the uncertainty and the scientific questions that we have to address through research so we can ultimately go back and make that prediction and make that estimate of the level of guarantee that we have got a safe product.

Senator COLLINS. Thank you.

Dr. Ostroff, it occurs to me that the increase in food imports, particularly of imported produce in this country, has allowed us to try exotic new fruit and vegetables that we would not otherwise have access to. It has also improved our ability to have year-around access to fruit and vegetables. But it seems to me that a down side is that it has exposed Americans to pathogens that we do not have any natural resistance to; that perhaps these pathogens are less of a problem in their native lands because they are indigenous, and the population over time has built up some sort of resistance.

How do we deal with this issue? Americans want these imported fruit and vegetables. They have given us variety in our diets, and they are supposedly healthy for us. But we are being exposed to emerging pathogens that we cannot even test; we do not even have the lab tests available for them.

What do we do?

Dr. OSTROFF. That is another excellent question, and I think that is the challenge that an agency like CDC has, because it is our job to be able to monitor for these types of diseases as they occur. Many of these changes in dietary habits are quite good for our cardiovascular systems, but they wreak havoc on our gastrointestinal systems in some instances. We know that certainly the spectrum of pathogens, or microbes, that cause gastrointestinal disease in tropical locations are quite different than they are in many temperate zones, like the United States. We are being exposed, and we are seeing outbreaks such as the one of *Cyclospora*.

I think another example of one that we probably would not have seen is the recent one in Chicago, where thousands and thousands of people became ill from an organism called enterotoxigenic *E. coli*—not the *E. coli O157:H7* that seems to get all the attention—that was related to potato salad coming from a particular deli.

We are seeing these new challenges. I am not sure I can state with absolute certainty that there is immunity built up in populations in tropical countries keeping them from getting the same types of illnesses from these pathogens that we do in the United States. I think that the systems for surveillance and monitoring and for diagnosis are not quite in place to the same degree that they are in places like the United States and other developed countries.

Certainly if you look at *Cyclospora*, this is an organism that was only first recognized in the 1970's, and it was recognized in, of all places, Papua New Guinea. It is only because somebody was looking that they even identified these cases, and have probably gone on for some period of time.

The only answer I can give you in terms of this particular challenge is that we need to have monitoring systems in place in this country so we can recognize these diseases and investigate them. I think, as importantly, that there are systems in place in the areas where these diseases naturally occur in the developing parts of the world so that we can identify, as was mentioned by Dr. Foran, what some of these risks potentially are even before they get here.

Senator COLLINS. Thank you.

Senator Lieberman.

Senator LIEBERMAN. Thank you, Senator Collins.

Let me pick up briefly on the last, very interesting line of questioning from the Chair. I gather that before 1996, cyclosporiasis was very rare in this country and was generally associated with people who traveled internationally; and now, it essentially rode in on the back of the raspberries. I am about to ask you the kind of questions that Senators ask, and I want to give you the opportunity not to answer it, but a question I have is are we reaching the limits of the possible number of new pathogens coming in here because of the globalization of our food supply that has already occurred, or is this going to go on without limit?

Dr. OSTROFF. Senator, that is a question that many people other than Senators also ask.

Senator LIEBERMAN. That is reassuring.

Dr. OSTROFF. It is an excellent question. In this whole area of emerging infectious diseases, if you look at the array of different diseases and microbes that we have discovered over the last 20 years, it is a very impressive group of pathogens.

Even in diarrheal diseases, if you just look at the diarrheal disease arena, if you were to take a large number of individuals who presented with diarrheal illness, and you sent specimens off to a clinical laboratory to look for the cause of their illness, in the large proportion of these people, the test would not show anything. We actually test for a relatively limited number of microbes when these specimens are sent off to the laboratory. Even in the research setting, if we were to apply the very best technology, all the razzle-dazzle diagnostics that we currently have available to us, in well over half of these individuals, we still cannot quite figure out what the cause of their diarrheal illness is. That does not mean that all of it is due to an infection. Some of it may be due to other kinds of causes. What it tells us is that there are still many bugs out there just waiting to be found, and in the same way that if we had done a study just like that in 1980, we would not have looked for *E. coli O157:H7* because we did not know it existed until 1981 or 1982, we certainly would not have looked for *Cyclospora* because we did not know it was there. There are still lots of them out there, waiting to be found, so, by no stretch of the imagination, have we reached the outer limits in terms of the things that we are going to see in the coming years.

Senator LIEBERMAN. So there is more to worry about and work on.

Also, as some of you indicated in your testimony, the number of reported cases is probably lower than the actual number of cases related to these pathogens that are brought in on food because of the difficulty of diagnosing.

I did want to ask Dr. Foran—I was quite interested in your own experience, and just very personally, people watching this may wonder what was the difference in the treatment you received, based on your own connection with the newspaper article about this outbreak, once you told your doctor that you thought you had a foodborne illness? In other words, was it a significantly different treatment from the original response?

Dr. FORAN. It was not just communication that it was a foodborne illness. We were able to be much more specific than that, because events moved so quickly. We suspected there was a foodborne illness, and shortly after we saw the article in *The New York Times* which identified *Cyclospora* and the symptoms associated with cyclosporiasis, at that point, it was absolutely clear what we had and what was causing our symptoms. And I think that around the same time—and it has been 2½ years now—that the CDC began to become involved in the investigation, and I believe there was enough information about the appropriate antibiotic—and I have been trying to remember what it was, and I cannot—but putting all that together, I was able to go back to my physician and say we have a confirmed outbreak of *Cyclospora*, here is the appropriate antibiotic, give it to me. In essence, he did, and the rest is history.

Senator LIEBERMAN. You are a great patient to have.

Dr. FORAN. Some might argue. [Laughter.]

Senator LIEBERMAN. In other words, there was a particular antibiotic that you needed to take that dealt with this rather immediately, much different from the general treatment that a doctor—a good doctor—would give a patient who came in with some of these symptoms.

Dr. FORAN. Well, I would guess that a physician, if he or she suspected a foodborne illness, would use a standard antibiotic if the level of suspicion were high enough. In this case, there was a specific antibiotic that was effective for *Cyclospora*, and it was a 5-day course, and once that is taken, it is resolved.

Senator LIEBERMAN. I do not want to make too much of this—but the difficulty in diagnosing is a problem because it affects the success of the treatment.

Dr. FORAN. No question, and the symptoms for cyclosporiasis were different than symptoms associated with most of the food- or waterborne pathogens that my physician and I assume most physicians were familiar with at the time—*Cryptosporidium, E. coli, Salmonella,* and so on.

Senator LIEBERMAN. Thank you.

Very briefly, I have questions for the two witnesses from CDC. First, a simple question—are you satisfied with the cooperation that our government has received from the Guatemalan Berry Commission?

Dr. HERWALDT. We have striven to work collaboratively with the Guatemalans. Again, we fortuitously had a field station and still have a field station in Guatemala which has facilitated this whole process. You can imagine it has not been an easy process because of the nature of what we had to work on together. We are having to work on trying to solve a problem related to outbreaks that have affected many people in the United States. Both sides have worked very, very hard to come together repeatedly and discuss what the issues are, to discuss how best to address them and to discuss where we should go from here. We have scientific constraints that we are dealing with, and we are working hard with the Guatemalans so they will understand why we do not have all the answers that they would like us to have.

It certainly has not been an easy process, but we are happy that the Guatemalans have been eager to talk with us and to continue the collaboration despite the fact that there are these difficult issues to deal with.

Senator LIEBERMAN. And am I correct that they are under no obligation to talk with the U.S. Government, any legal obligation, that they are doing this voluntarily, I presume, with an economic motivation, which is that if they do not give some reassurance, the Guatemalan berries are not going to sell very well in the United States.

But let me come back to my first question. Am I right that these are discussions and cooperative efforts that are going on voluntarily between our government and the Guatemalan Berry Commission?

Dr. OSTROFF. That is correct.

Senator LIEBERMAN. And I ask the question just to draw attention to the point that there is no existing statutory authority as I understand it for the U.S. Government to apply standards, safety standards, sanitary standards, for the production of produce, fruit and vegetables, and I guess grains, too, in foreign countries, as compared to the authority that I believe the U.S. Department of Agriculture has with regard to meat and poultry.

Is my understanding correct?

Dr. OSTROFF. Senator, it would be best to have that answer from the Food and Drug Administration because this is in their sphere. My understanding—and again, I will emphasize, my understanding—is that your presumption is correct.

Senator LIEBERMAN. Maybe I should turn to our staff witness, Dr. Smith. That is correct, isn't it, that at the current time—and this is why we have the calls for the so-called equivalent authority——

Dr. SMITH. Equivalency, correct.

Senator LIEBERMAN [continuing]. To give, presumably, FDA, or maybe some part of the United States Department of Agriculture the same authority that they have with regard to meat and poultry to certify the production standards in foreign countries, to give them that same authority with regard to fruit and vegetables.

Dr. SMITH. It is important to understand that under the GATT agreements, we already have the authority to—that we have the sovereign right is the way it is stated—to inspect food that we import into this country to meet our level of protection, however that is defined.

The challenge comes in how we define that level of protection.

Senator LIEBERMAN. And how do we enforce it.

Dr. SMITH. And how do we enforce that so that it is met domestically before we can impose it internationally. In this situation, the Guatemalans have voluntarily allowed our U.S. Government agencies to go into their country and work with them, so we have not had an issue there, but that might not be the case with other countries.

Senator LIEBERMAN. You made a good point, that the standard with regard to meat and poultry is that the country of origin has to have sanitary and safety standards comparable to ours. Is that right?

Dr. SMITH. That is correct.

Senator LIEBERMAN. Now, I am interested in what you said about GATT. Theoretically, if we were concerned that fruit and vegetables were coming in from a country that had deficient standards, we could initiate an action at the World Trade Organization?

Dr. SMITH. We need to establish, though, that we do it domestically, and currently, as far as agricultural practices, the FDA is developing guidance on that, but there are no formal standards or regulations in place.

Senator LIEBERMAN. And I gather, incidentally, as a matter of note, that only 37 countries, interestingly, have passed the USDA test with regard to meat and poultry, so a standard has been applied that not everybody has met.

This is one constructive way that we in Congress can go forward, which is to give more detail and substance to what is implicit in the GATT agreement by adopting legislation that gives us equivalency authority to hold producing nations to standards comparable to their own if we are going to allow their fruit and vegetables to come in, understanding that the more we go into this, the more complicated it gets. It is not easy, but we can raise the standard so there is a higher probability that the farms that they are grown on the places where they are handled will be at higher sanitary levels, and therefore, it is less likely that they will be bringing in foodborne illness. I think that may end up being the challenge for us. Now, how we implement that and whether we have to put inspectors in foreign countries and have their agreement to that is a topic for another day.

You have all been excellent witnesses, and I thank you very much for your contributions.

Thank you, Madam Chair.

Senator COLLINS. Thank you, Senator Lieberman.

I have just a couple quick questions before I yield to Senator Durbin. Although the United States does not currently have an equivalency system for fruit and vegetables that parallels the Department of Agriculture system, does the FDA currently have authority to ban foods imported from other countries that they believe are unsafe, and has that happened in the case with the Guatemalan raspberries?

Dr. Ostroff.

Dr. OSTROFF. As I mentioned in my testimony, Senator Collins, and I think you mentioned this earlier, my understanding—and again, it would be up to the FDA to provide more detailed information—is that they cannot ban the export, but they can restrict the import. This is what they actually did, and they indicated that they would not permit raspberries out of the ports between certain dates, March 15 and August 15. That was based on the epidemiologic information that was accumulated in 1996 and 1997 about when the risk period was for the outbreaks in the previous years.

Senator COLLINS. That is my understanding as well, that initially, the Guatemalan Government on its own suspended shipments, but that subsequently, the FDA said that it would not allow imported raspberries from Guatemala to enter the American marketplace until its concerns were resolved; is that accurate?

Dr. OSTROFF. Right, and that letter was sent out in November of last year.

Senator COLLINS. Thank you for clarifying that point.

Senator Durbin.

Senator DURBIN. Thank you, Madam Chair.

I appreciate the testimony here today, and I read through it, but I am sorry I could not be here for the oral presentation in its entirety.

Let me first address what I consider to be an overarching issue here, and I would like to have the comments of those who are involved in this. I think that one of the major problems we face in terms of food safety in this country is proliferation of Federal agencies with jurisdiction. There are some 12 different Federal agencies and 35 different laws that govern food safety and inspection.

As a case in point, this raspberry investigation that we have showcased today involved at least four different Federal agencies, each with specific jurisdiction over some part of the investigation.

I have introduced legislation in S. 1465 to try to replace this fragmented food safety system with a single, consolidated, independent agency with responsibility for Federal food safety activities.

I would like to note that in the last hearing before this Subcommittee on food safety, we learned that some of the computer systems that are used in U.S. ports of entry were not compatible. CDC, FDA, and USDA have developed a cooperative food surveillance project called FoodNet for foodborne disease.

I would like to ask the panel, are the computer systems integrated such that each of the agencies has access to the latest information on outbreak investigation?

Dr. OSTROFF. Senator, not being aware of all the computer system, I think the best answer I can give to that that exist currently, through some of the activities that have gone on as part of the President's National Food Safety Initiative, the interagency food safety initiative, we have a much closer level of cooperation. For instance, any information that the USDA has concerning contamination of meat products, they immediately send us either by computer or by fax, telling us of any potential recalls. We also inform them of any investigations that we are conducting. We tend to give them this information even before we know whether they are foodborne or not. We know with many of the foodborne pathogens, even with salmonella, that sometimes we will conduct investigations, and we will find out that the source is not necessarily a foodborne source. Witness the recent experience that we had with the swimming pool outbreak of *E. coli O157:H7* in Atlanta.

There is a much greater degree of cooperation among the agencies in terms of information-sharing than there used to be. In many ways, it is actually more useful to pick up the telephone or to send specific information than to have to wait to massage data through a computer system.

Senator DURBIN. I think we have made some progress. I think we have a long way to go. I hope that by consolidating this into one agency that this communication will take place. Let me give you an illustration.

As I understand the Food and Drug Administration process on fresh fruit and vegetables brought into the country, samples are taken at border ports and then sent to FDA laboratories for investigation. I have gone through this process, and once having arrived, for example, in Nogales, Arizona, the sample is sent off to the Los Angeles lab. The Los Angeles lab receives it a day or two later. When the shipment is on its way to some store, the lab is usually in the process of investigating it. As we have established here, the lab is not going to detect the *Cyclospora* problem that we have discussed. As I understand the testimony, there is no known means of detection. The lab takes a look at these samples for suspected problems, and they have to start with a suspicion, because the universe of possibilities is almost unlimited. So they start with a suspicion that it might have an insecticide, a herbicide, a pesticide, something on it that it should not have, and therefore might be problematic. And again, let me confess that, being a liberal arts major, I get lost here in a hurry, but they set up their calibrated equipment to look in certain spectrums of chemicals to find their presence on the fruit and vegetables—and this is leading to a question—if they find it, they have noticed that some shipper and some producer have a problem. And once that is established, that shipper and producer are treated a little differently in the future. They start looking more closely, holding shipments for further inspection before they are released at the border, and in the worst case scenario, actually requiring proof that the shipments are clean before they can go forward from the border.

In this situation, when we are dealing with a foodborne illness like the *Cyclospora* problem, since it cannot be detected at the outset, about the only thing of value is to try, as we have in the Guatemalan raspberry situation, to trace back and find out whether there is a problem area in some part of the world that requires some type of effort by the United States to reduce risk.

Dr. Smith, one of the problems as I see it in this situation is that raspberries are usually pooled before they are shipped, and that makes it more difficult to identify the source farm where there was an outbreak. Do you believe that pooling harvested fruit before shipment adversely impacts traceback efforts?

Dr. SMITH. Well, it certainly complicates the efforts. I really do not see how we could get around pooling. We do that here, too. That is just how you fill orders—although I believe the Guatemalans are implementing a tracking system where they will actually be able to tell on any shipment which farms the berries came from. So there are some systems we could put in place to facilitate tracebacks.

Senator DURBIN. That was my next question. I wonder if you believe that bar-coding the shipment, for example, as to the farm sources, so that when the shipment is received, if in fact we find a problem 2 weeks or a month later that could not have been detected by any type of reasonable inspection, we at least then know the source farms to go back to, and we can try to retrace the steps and find out what the problem might be and work with the country of origin to reduce it.

It is an investigative tool which I think might be helpful. You say they are in the process of doing it in Guatemala. Are other countries moving in this direction?

Dr. SMITH. I really do not know about other countries. I would suspect, though, that once one country does it, it is going to be something that other countries will consider.

Senator DURBIN. Having said that, going back to our discussion about trade standards, I have probably just invited the same standard to be applied to the United States exports, and there may be some people who say it is inevitable, and others who ask why did you bring it up—now we have to go through the same kind of thing. But in the scheme of things, when we are talking about so much fresh produce being exported from country to country it strikes me that this is inevitable, that since we cannot detect it in the clamshell baskets, once having discerned the problem, we can at least get back to the source.

I wonder—you made a reference earlier in response to Senator Lieberman's question—do you think that establishing this kind of standard would be consistent with the trade agreements and the phytosanitary sections of those agreements?

Dr. SMITH. Establishing——

Senator DURBIN. The bar codes on source farms.

Dr. SMITH. I think the way that it works is that it is negotiable bilaterally with a particular country, but I know that transparency is important, and if you are openly discussing what measures you think are important, I believe that would fall under GATT agreements.

Senator DURBIN. Let me ask you about the whole HACCP revolution that is taking place in terms of food inspection, which is relatively new on the Federal scene. Is the implementation of a HACCP-based approach to reduce the risk of foodborne illness an effective approach with respect to the Guatemalan raspberries and imported foods in general? That question is for anyone.

Dr. FORAN. I will be glad to start. HACCP is an approach that implements technologies at particularly sensitive points along the process, for example. It is called the Hazard Analysis Critical Control Point approach.

I believe it is a useful approach for reducing hazard-associated with foodborne pathogens, but I argue very strongly that it is ineffective without a risk-based component to it. If we implement a technology at a particular control point and assume we are being effective in reducing hazards, we are just guessing at that point.

We need a risk-based component so that we can quantitatively estimate how effective that technology is at the particular control point and then determine have we been effective enough, or do we need to implement technologies at other control points, or do we have to ban import of the product. But without a quantitative risk assessment or an estimate of the quantitative estimate of reduction in risk, I think HACCP in and of itself will not be effective.

Senator DURBIN. Tell me what you mean when you use the term "quantitative risk assessment."

Dr. FORAN. It means an estimate, a probabilistic-based number of how many people will become infected or what the risk of an individual is when they eat a raspberry that may have *Cyclospora* on it. It is a predictive estimate of the risk that someone faces when they eat a product.

Senator DURBIN. So the suggestion is that before a public health initiative, we measure what the cost would be absent the initiative.

Dr. FORAN. Cost is another issue, and risk assessment can help us understand cost and enlighten the issue of cost, but risk assessment does not provide estimates of cost. It simply provides estimates of disease probability. The cost issue, then, can come in around the issue of suppose the technology that we are going to implement under HACCP costs "x" dollars; if we have a risk assessment to go along with that, we can make a determination of whether we want to spend that amount of money to get the requisite amount of risk that we predicted with the risk assessment process.

Senator DURBIN. We debate this term "risk assessment" on this Subcommittee, and there is a lot of difference of opinion here about what it means, and I for one worry about cost as an element in risk assessment and what it means.

Your experience with foodborne illness was obviously troubling and discomforting, but not disabling, and I take it you have made a full recovery; but a person who is more vulnerable—a child, an elderly person, or someone with a compromised immune system—could have gone through a much more difficult experience.

Dr. FORAN. I think that is likely, and I will turn to Dr. Ostroff, but I am not aware that we know enough at this point about variability in human susceptibility associated with the severity of disease, cyclosporiasis. That is a big unknown right now, and it is a critical data gap that I think we have got to fill if we are going to do a better job of understanding the risk posed by *Cyclospora* and other foodborne pathogens.

Senator DURBIN. That, of course, is part of the debate here that will continue as to how do we quantify these risks. If we want to really get down to the bottom line, as we call it, and say how many dollars are at stake here, how many trips to the doctor are acceptable before we can impose a new standard by law, how many deaths are acceptable before we impose a new standard by law, how much cost to society and how much cost in terms of public health before we impose a new standard, a new law, I think that is very troublesome, and as a Member of the U.S. Senate, I think this is too close to the "God squad" assignment as far as I am concerned. I think that we have historically decided to err on the side of caution when it comes to public health and safety, and we are now calling in the accountants to help us make the decision. I think there are times when we may make the wrong decision and later find that we have an unfortunate occurrence.

Dr. FORAN. Senator, I would simply suggest that in my mind, there is a big difference between cost-benefit analysis and risk assessment. I think risk assessment is a critically important tool to help us understand the hazards or the probabilistic expression of risk to help us understand the issues that are associated with being infected and having a disease caused by exposure to a pathogen. Cost-benefit analysis, technology issues—those are all separate. There is a linkage there. They help each other, I think. They can work in concert. But if we are not conducting risk assessment, if we are not gathering the information that we need to conduct risk assessment, we are doing ourselves a disservice because we are simply guessing about all the other issues, about whether it is an effective technology, whether we can rationalize the cost, whether we even have acceptable or unacceptable risk. These are all guesses unless we have a good, strong, quantitative, scientifically defensible approach to understanding risk.

Senator DURBIN. And you get down to the bottom line—and someone on the panel made reference to it earlier—we now have a choice between cardiovascular health and gastrointestinal health, and the question that may come from this hearing for anyone who is following it closely is, all right, let us get to the bottom line here—is it better that I eat the fresh produce even though I cannot be certain of its safety—is that better for me in terms of my health, or is the risk too high in terms of possibility of foodborne illness that I should steer away from it and not eat the fresh produce.

Dr. FORAN. There is an analogy, which I am sure you are familiar with, with regard to contaminated fish. The argument has been that we should not eat some fish because they carry high body burdens of chemicals. Of course, we are not getting the benefits of fish if we do not eat fish. How do you deal with that?

I would argue that we should not stop at that level of the argument. Why not take steps to make sure that the chemical burden in fish is low enough in all fish so that they are all safe to eat, and we do not have to worry about this? And I would suggest that the same argument applies here. Why not take steps as best we can to reduce the pathogen burden on the product so that we do not have to worry about tradeoffs like cardiovascular health and other kinds of health issues.

Senator DURBIN. Thank you very much.

Thank you, Madam Chair.

Senator COLLINS. Thank you, Senator Durbin.

I want to thank all of our witnesses for their very valuable assistance today. Today's hearing has focused on a specific case study of tainted imported fruit. The intention was to highlight the challenge we face in our effort to improve the safety of imported food. I believe the hearing today has underscored the fact that the safety of imported food is a growing problem, especially with respect to emerging foodborne pathogens, and that finding an effective solution is very difficult when we are dealing with pathogens that cannot be visually detected by consumers, removed by washing the fruit involved, or in some cases, such as *Cyclospora*, even detected through laboratory tests on the fruit in question.

I mentioned in my opening statement that this hearing is the second in a series of hearings the Subcommittee will be holding on the safety of imported food. The Subcommittee will hold two more hearings; the next one will focus on fraud and deception in the import process, and our final hearing will focus on remedies and solutions. We will give Members of Congress, the Executive Branch, and consumer and industry groups the opportunity to provide recommendations for improving our Nation's food import system. Our intent is a careful and thorough examination that will provide the foundation for effective reforms to improve the safety of imported foods.

As I mentioned, the difficulty of our task is underscored by the fact that we have had two outbreaks of *Cyclospora* associated with imported raspberries in the United States, and right now, our neighboring country, Canada, is dealing with a very similar outbreak.

I appreciate the contributions made by all of our witnesses. We would also welcome any suggestions that you might have on specific legislative recommendations; that would be very helpful to our records as well. The hearing record will remain open for 10 days.

Again, thank you all for your contributions to our effort.

I would also like to thank the staff of the Permanent Subcommittee on Investigations, including Tim Shea, Dr. Stephanie A. Smith, who has done an outstanding job for us, Don Mullinax, Lindsey Ledwin, Mary Robertson, and the entire staff, for their assistance.

Thank you very much. This hearing is adjourned.

[Whereupon, at 12:10 p.m., the Subcommittee was adjourned.]

APPENDIX

PREPARED STATEMENT OF MAX CLELAND, A U.S. SENATOR FROM THE STATE OF GEORGIA

The safety of our families' food is critical to each of us. America's farmers have long supplied the country with nutritious, disease-free produce. In the United States, we have come to take for granted that the food we eat is clean and safe. In almost every instance, it is. We in Congress need to take prudent precautions to be sure that it stays safe. Increasingly, fresh produce is available throughout the year from growers in other countries, some of which do not impose the high public sanitation standards in force in the United States. It is important, therefore, we ensure that the food we serve to our children, from whatever country of origin, will not make them sick.

There are, however, other factors to be considered in our attempts to control the produce growing conditions of other nations. If we act impetuously, we may inadvertently jeopardize relations with our trading partners. Just as the United States imports food to satisfy demand, other countries import U.S. agricultural products. These exports are an important market for U.S. farmers. We must also seek to maintain the best possible diplomatic relations with our neighbors in the Western Hemisphere. As we work with these countries to reduce the production of illegal drugs which find their way into our country, one of the solutions is to introduce other crops as profitable alternatives for the growers. It is important to keep diplomatic channels open and work together to solve problems in imports.

I thank the Guatemalan High Level Commission for Food Safety for their cooperation with the Center for Disease Control in finding the cause of the cyclospora outbreaks and for their written statement for this hearing. Guatemala and the United States have been able to work together to pursue solutions to both the health and economic problems presented by the outbreak. This cooperation benefits both countries. We must be careful, however, that in our attempts to regulate food safety we do not provoke retaliatory actions by our trading partners. We must also be sure that we do not impose expensive, unnecessary restrictions on U.S. farmers in our food safety efforts.

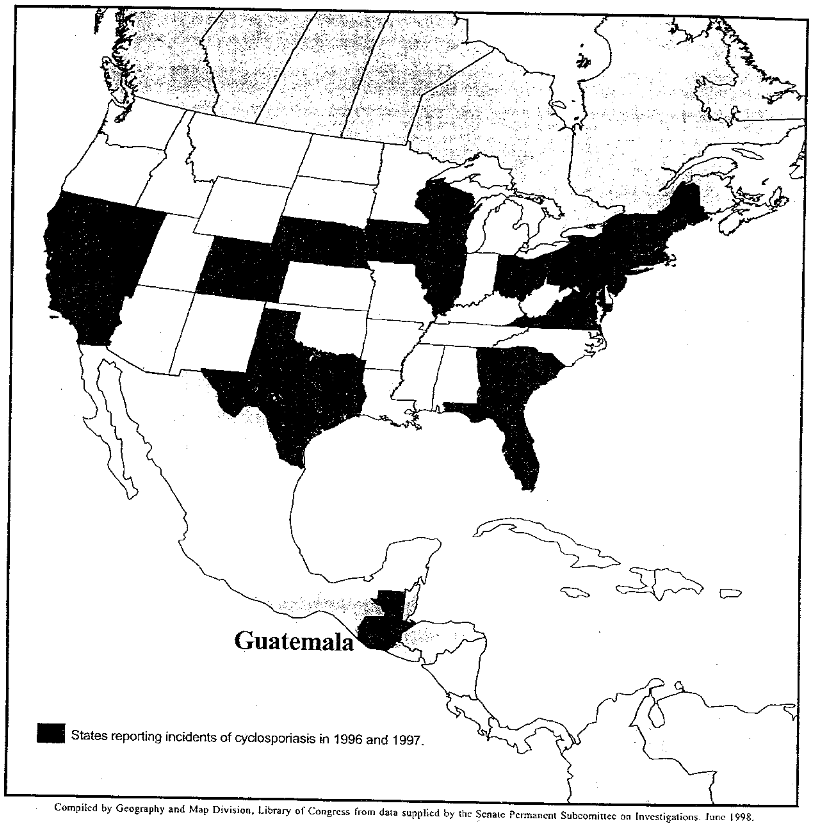
I thank the Chairman for these hearings. They are an opportunity to discuss ways to be sure that our food is safe while at the same time maintaining our agricultural presence in the global economy.

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 1

1996 and 1997 Cyclosporiasis Outbreaks

Areas Affected in the U.S.


Guatemala
■ States reporting incidents of cyclosporiasis in 1996 and 1997.

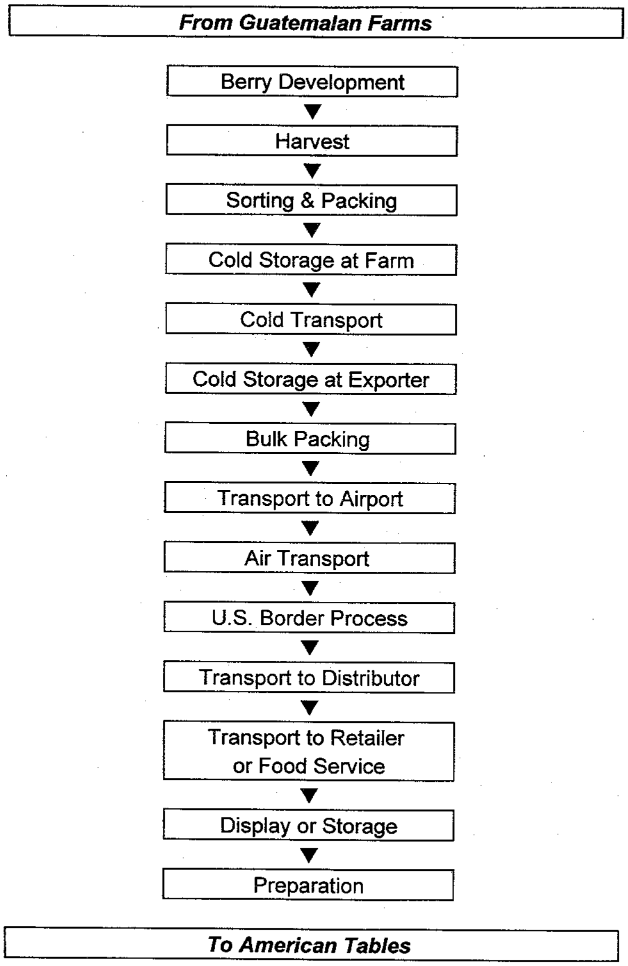
Compiled by Geography and Map Division, Library of Congress from data supplied by the Senate Permanent Subcomittee on Investigations. June 1998.

50-357

Senate Permanent Subcommittee
on Investigations

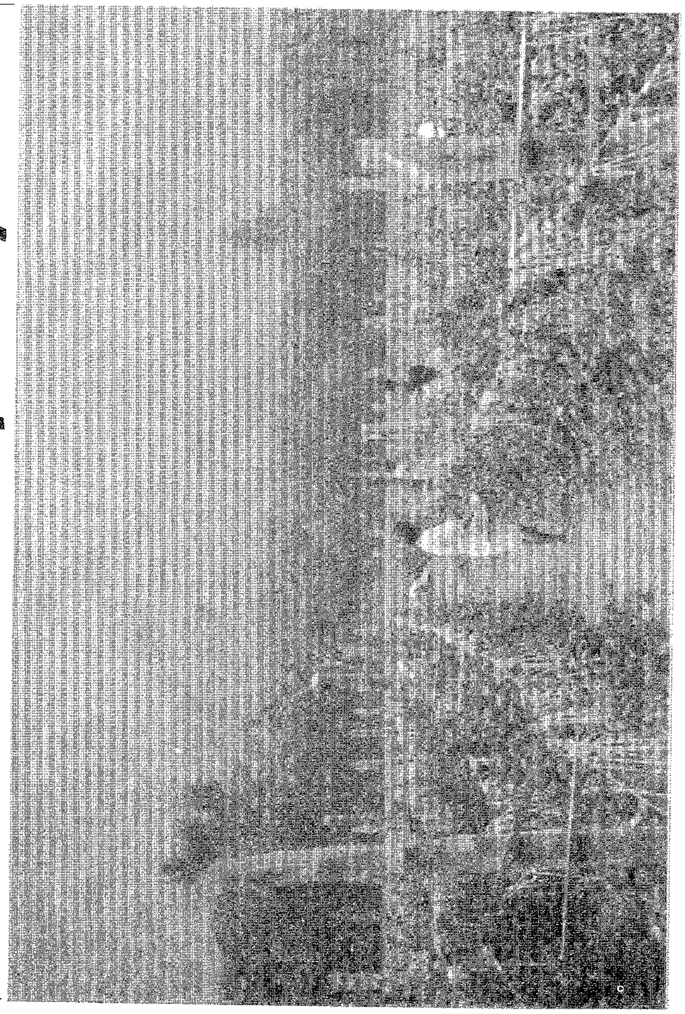
EXHIBIT # 2

Fresh Raspberries from Farm to Table



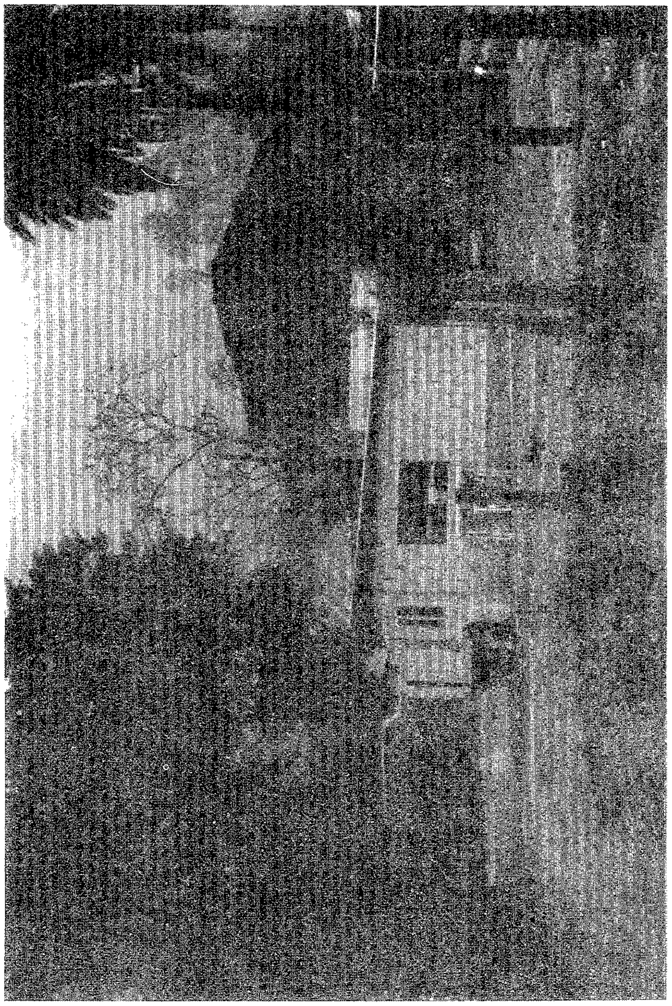
Dr. Smith Testimony: Photograph #1

Dr. Smith Testimony: Photograph #2



Guatemalan Raspberry Farm

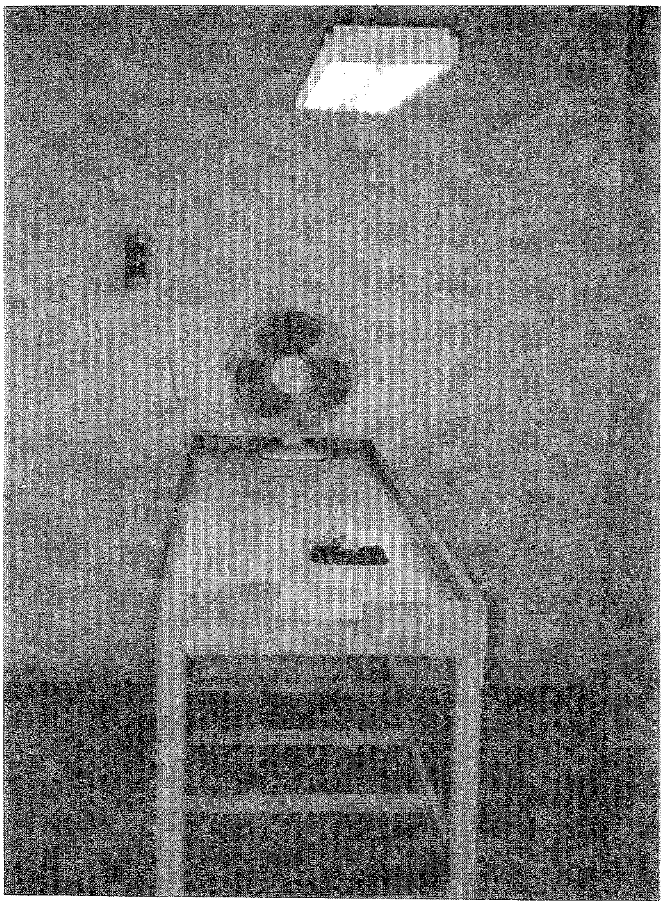
Dr. Smith Testimony: Photograph #3



Guatemalan Raspberry Farm

Dr. Smith Testimony: Photograph #4

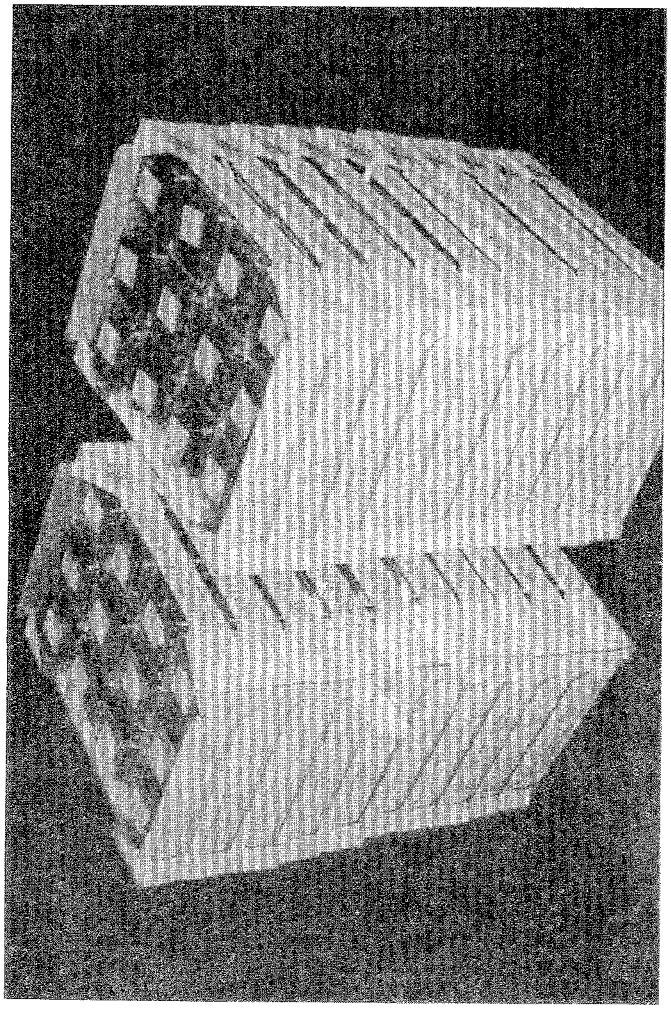
Sorting Table



Dr. Smith Testimony: Photograph #5

Dr. Smith Testimony: Photograph #6

Raspberry Flats



Dr. Smith Testimony: Photograph #7

Port of Entry

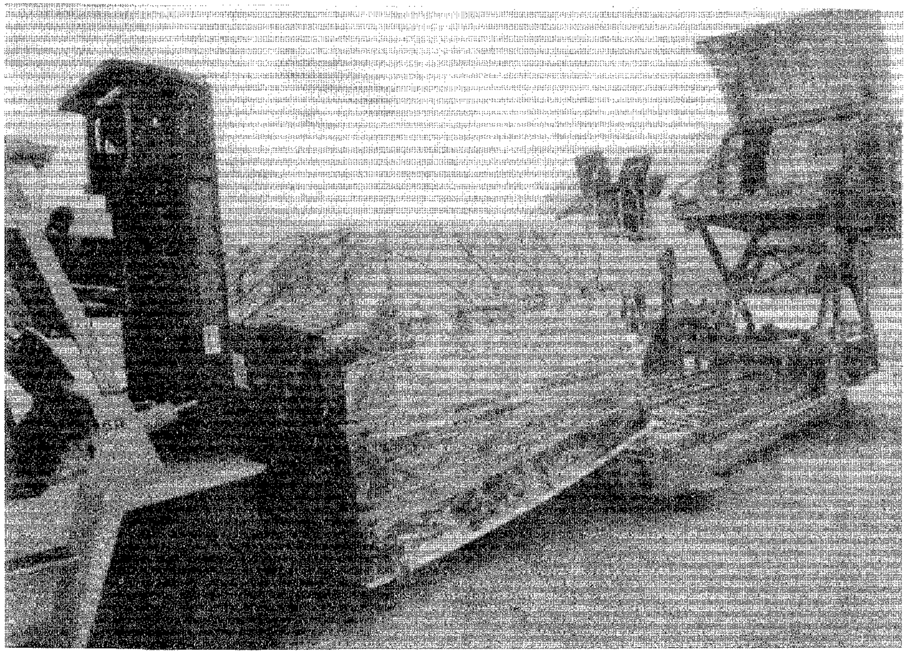


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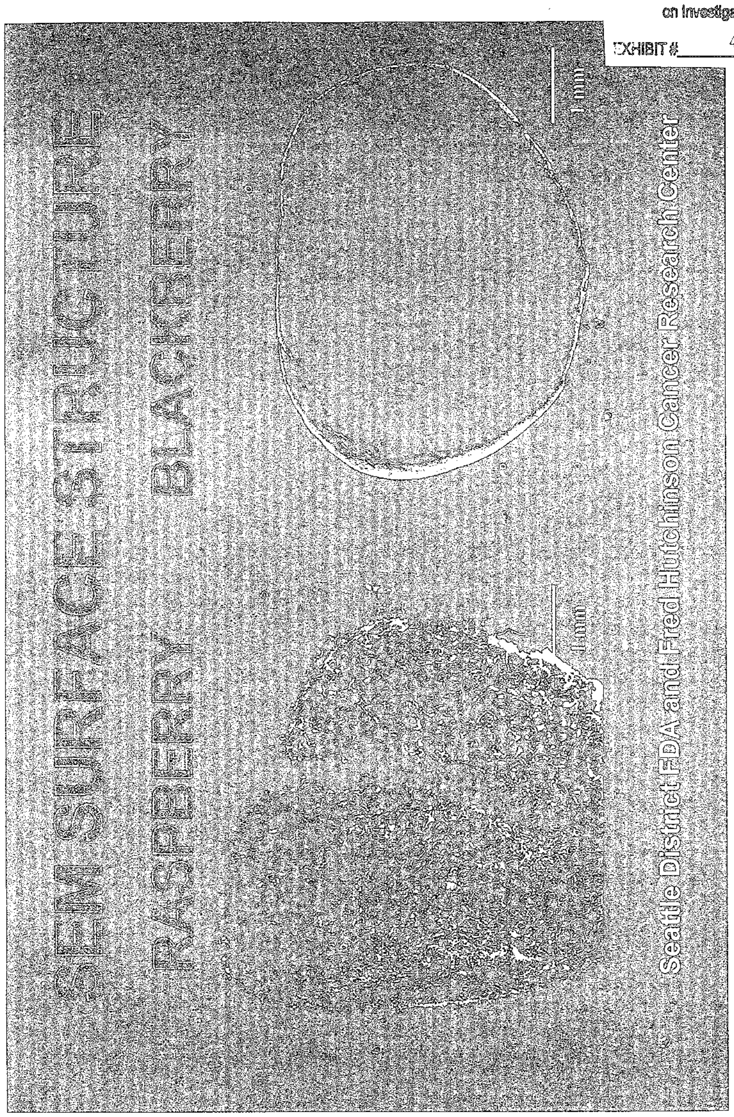
EXHIBIT # 4



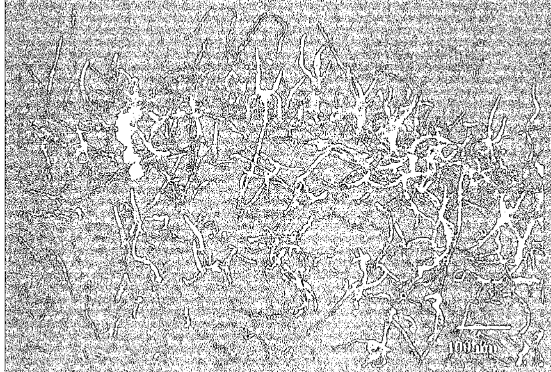
SEM SURFACE STRUCTURE

RASPBERRY BLACKBERRY

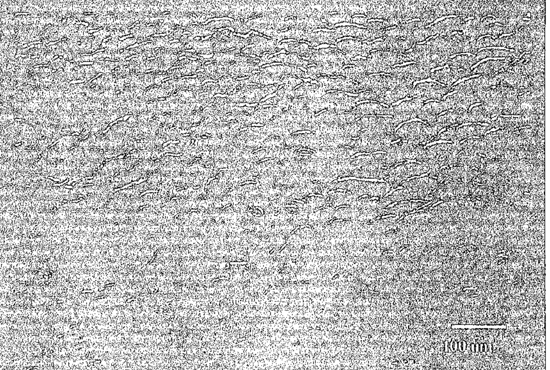
Seattle District FDA and Fred Hutchinson Cancer Research Center

SEM SURFACE STRUCTURE

RASPBERRY



BLACKBERRY

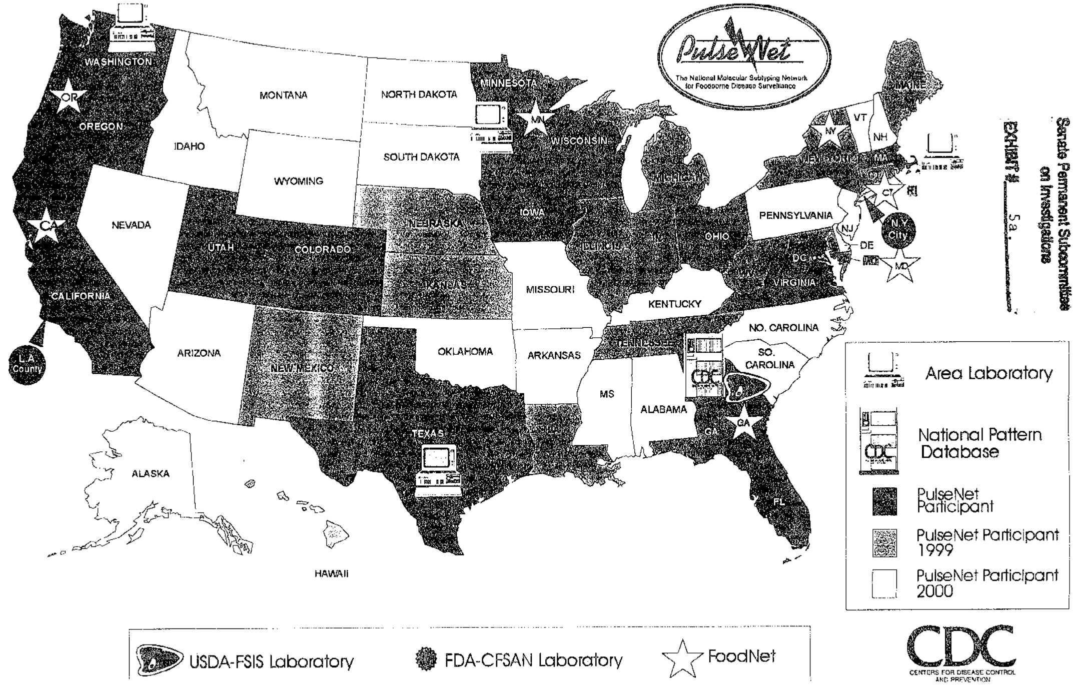


Seattle District FDA and Fred Hutchinson Cancer Research Center

The National Molecular Subtyping Network for Foodborne Disease Surveillance

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 5a.



CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Senate Permanent Subcommittee
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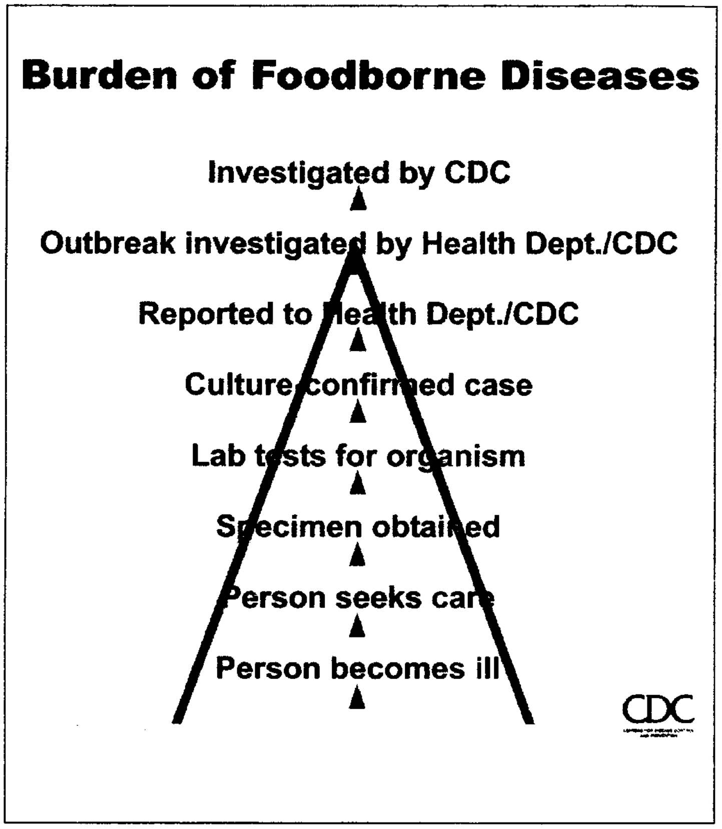
EXHIBIT # 5b.



Burden of Foodborne Diseases

Investigated by CDC
▲
Outbreak investigated by Health Dept./CDC
▲
Reported to Health Dept./CDC
▲
Culture-confirmed case
▲
Lab tests for organism
▲
Specimen obtained
▲
Person seeks care
▲
Person becomes ill
▲

Senate Permanent Subcommittee
on Investigations
EXHIBIT # 6

WRITTEN STATEMENT

OF THE

GUATEMALAN HIGH LEVEL COMMISSION FOR FOOD SAFETY:

"BERRY PRODUCTION IN GUATEMALA"

PRESENTED TO THE

SENATE PERMANENT SUBCOMMITTEE
ON INVESTIGATIONS

UNITED STATES SENATE
WASHINGTON, D.C. JULY 9, 1998

The Guatemalan High Level Commission for Food Safety is pleased to have received the opportunity to present before the Senate Permanent Subcommittee on Investigations, its written statement in reference to the Subcommittee's hearing on food safety.

The High Level Commission for Food Safety was created in late 1997 to develop an oversight framework to ensure that Guatemala's agricultural exports meet the highest sanitary and quality standards. The Ministries of Agriculture, Health and Economy preside over the Commission, while the Non-Traditional Products Exporters Association (AGEXPRONT), with support of the Guatemalan Berry Commission (GBC), coordinates the day to day activities.

With the advent of cyclospora outbreaks in the United States of America (U.S.), the Commission made cyclospora its priority issue. Historically, the Center for Disease Control (CDC) first reported cyclospora outbreaks in the U.S. in 1990. The first outbreaks, in Chicago and New York, were linked to water. However, it was not until 1996 and 1997 that fresh produce consumption – including Guatemalan raspberries – was epidemiologically linked to cyclospora cayetanensis in some of the outbreaks.

CDC and Food and Drug Administration (FDA) scientific data show that there is imprecision regarding the source, biology and virulence of this little known emerging pathogen. It has not been detected in raspberries or in any common practice involving any of the procedures in raspberry growing, handling, or exporting.

Nevertheless, FDA's and CDC's reports stated that it seemed to be a seasonal illness, occurring during spring and early summer seasons. Based on their findings, Guatemala decided to voluntarily suspend the exports of raspberries to the U.S., and thus facilitate the gathering of additional scientific information. It is noteworthy to mention that in the past three years (1996, 1997 and 1998) Guatemala has exported approximately 400,000 raspberry flats during the late summer, fall, and winter seasons without incident.

Guatemala has fully cooperated with CDC and FDA officials in their investigations to find a solution to this worldwide problem. Since 1997 Guatemalan raspberry growers have taken a proactive stance to find the source of contamination. It started to implement sanitary and quality assurance systems in raspberry farms with the cooperation of FDA, CDC and the Food Marketing Institute (FMI).

In this regard, the Commission comprises several working groups, but the most important ones relate to the following areas:

i. Research, epidemiology and environment
ii. Post-harvest treatment evaluation, and
iii. Inspection, certification and verification of farms and exporters' plants by the Agricultural & Environmental Integral Protection Program (PIPAA) - a public and private sector joint commission.

Within these working groups, the Commission has incorporated expert oversight groups that include the CDC, FDA, international scientists, and universities.

In addition, and with the Commission's support, the GBC has implemented a Sanitary and Quality (S&Q) Assurance Program, that takes into account Hazard Analysis of Critical Control Points (HACCP), and Good Agricultural and Good Manufacturing Practices (GAP/GMP) standards. This program is even stricter than the FDA's future GAP/GMP Voluntary Guide for Fresh Fruit and Vegetables.

The program is made up of four well-defined subject areas:

I. Minimum Requirements Guideline for Production and Export of Raspberries

II. PIPAA's Grower & Exporter Classification and Risk Assessment Data Bases; and Inspection, Monitoring, and Program Quality Control Activities

III. Trace-Back Capability

IV. Bi-Ministerial Compliance Agreement

Subject area I establishes HACCP, GAP/GMP, Water Quality, Infrastructure, and Transportation Standards. The implementation of a HACCP system resulted in the strongest contribution to the sanitary and quality control of the product. By establishing Critical Control Points on the farms' and exporting plants' processes and transportation, the producer is able to have better control while aiding in the development of a high standards system. It also provides clear guidelines on the general practices such as water supply, hygiene, irrigation, fertilizer and pesticide utilization, harvesting, packaging, and storage and distribution of product, among others.

PIPAA established the framework for the classification of the farms through the elaboration of databases with updated information regarding the location and specific production areas of farms, water sources and irrigation, pesticide utilization, infrastructure, and exporters' plants. Based on the collected data, PIPAA is able to assess the farms' compliance to the S&Q Assurance Program, and classify farms and plant facilities in risk levels -- high, medium, or low.

Consequently, some of these data is then captured in bar codes that allow for the trace-back of the product's origin. To further strengthen the S&Q Assurance Program, a Bi-Ministerial Compliance Agreement between the Ministries of Agriculture and Economy, was approved to provide the regulatory structure for the production and export of raspberries.

Furthermore, as a result of the studies that point to the seasonal nature of the problem, the High Level Commission for Food Safety presented recently a unique proposal to the FDA called the "Model Plan of Excellence" (MPE). In it, additional stricter measures to those established in the S&Q Assurance Program are formulated with the object of identifying and qualifying specific farms for the all-year-round export of raspberries.

In addition to the standards in the S&Q Assurance Program, the MPE calls for additional employee training on health and hygiene principles, monitoring of employees' health for the eradication of potential risk factors, and further control of the fruit's origin. The latter implies stricter PIPAA farm, shipment points, and transportation inspections. The MPE also regulates the proper issuance of export licenses to the selected exporting plants, and also conducts origin-verification inspections at a one of a kind import/export airport warehouse facility for the handling of air shipments. In order to strengthen the trace-back capability, a trace-through function is added to track the product to its destination.

The MPE also provides guidelines for the selection of farms. Those low risk farms classified by PIPAA that obtain the highest scores in the implementation of the S&Q Assurance Program and whose personnel exhibit expertise in the application of these principles at farms and plant facilities, may export throughout the year.

As part of the MPE approval process, and based on FDA's current scientific information that cyclospora is a water borne fecal contaminant, FDA officials conducted in-situ inspections at various low risk farms and selected three farms whose infrastructure had the capability of meeting the MPE's strict requirements. However, it emphasized that prior to their full certification for export throughout the year, the farms had to thoroughly implement the following MPE requirements that FDA considers key to ensure the inocuity of the fruit: installation of filters at all water sources, high hygiene levels at farms and processing plants, and monitoring of employees' health for the eradication of potential risk factors.

FDA's final certification of these farms will result in the creation of a model farm that will serve as a tool to encourage other low-risk farms to implement the MPE's strict requirements if they want to export throughout the year.

As a closing remark, the Guatemalan High Level Commission for Food Safety would like to state that it is not only determined to fully implement and observe the MPE's compliance, but to sustain the effort and perfect the program accordingly to respond to new challenges. Also, it feels that this unique kind of inter-governmental cooperation already serves as a cornerstone for programs worldwide, and that only through this kind of true cooperation will the governments be able to ensure the well-being of the consumers in this age of global trade.

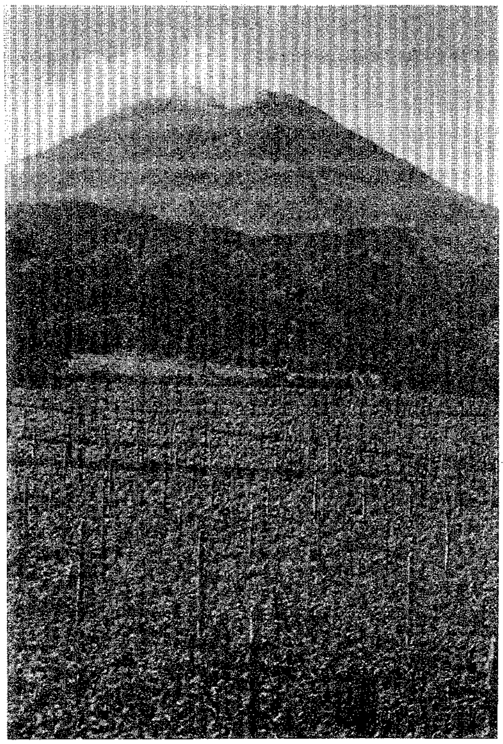
Thank you.

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 7

Guatemalan Berries

Spring-Summer 1998



An active volcano near Parramas, Chimaltenango, Guatemala, overlooks the young San Miguel berry plantation of HortiFrut, one of Guatemala's berry export companies.

A POSITIVE FOOD SAFETY EXAMPLE FOR THE WORLD

Perhaps, or perhaps not, for good reason, a siege on Guatemala's berry industry was launched in the spring of 1996. Statistical, and *only* statistical evidence, indicated a good chance that the eggs, or oocysts, of the Cyclospora protozoa were carried on Guatemalan raspberries to consumers in the United States. No other countries reported similar problems. Consumption of those oocysts gives humans diaherrea.

By Law, A HACCP System Is Required for Guatemalan Berry Exports

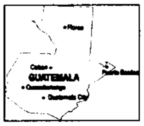
Thousands of subsequent scientific tests have not revealed any physical evidence that Guatemalan berries have ever been associated with the oocysts. The statistical evidence not only left a huge loss in finances but also lost reputation for Guatemalan raspberries. Worse, Guatemalan blackberries and other produce suffered lost prestige.

To resolve the crisis, the Guatemala Berry Commission (GBC) presumed the statisticians might have been correct. Thus, the GBC implements all recommendations from the Food & Drug Administration (FDA) and the Centers for Disease Control (CDC) to assure shipping the world's safest fruit. Guatemala's Ambassador to the U.S., Pedro Lamport has worked diligently to represent his

(Continued on page 3)

GBC Cooperating, Communicating

The Guatemala Berry Commission (GBC) is cooperating on a number of fronts to protect its reputation and build an understanding in the U.S. of what is happening within its industry.



The GBC is working in Guatemala on the Inter-Ministerial Committee to assure that the publicity tying Cyclospora and Guatemalan raspberries is not confused with any other foods exported from Guatemala. Also called the *High Level Commission*, the group is composed of the Guatemalan Ministries of Health, Economy, Agriculture, and a private group, Agexpront, the exporters' Chamber of Commerce. One health official said of this group: "The (Guatemalan) government has taken an up-front role in addressing the issue of food safety. This is orchestrated at a level that is very positive, with implications going way beyond raspberries. Food safety is within the entire portfolio of Guatemala for produce exports. We're out in front of most the countries exporting to the U.S."

In January, the GBC also accepted an offer of voluntary support from Dr. Tim Hammonds, the President of the Food Marketing Institute, (FMI) Washington, D.C.

FMI represents thousands of supermarket chains in the United States and other countries. Dr. John Farquhar, a food scientist with decades of experience on such matters, and the FMI liaison to the GBC, is working with the GBC, the Guatemalan Embassy in Washington, D.C., and the Food & Drug Administration, also in Washington, to find a fair plan to help allow Guatemalan berries to be shipped this spring. This would counter an FDA statement in late 1997 indicating that no Guatemalan raspberries could be exported to the U.S. between March 15 and August 15, 1998.

Guatemala: A Berry Special Country!
Healthy Berries for the World!

Farquhar credits the FDA for being very cooperative and positive. He expects a satisfactory scientific arrangement that will not only assure that U.S. consumers will not become ill from Cyclospora, but preserve Guatemalan raspberry economic viability.

The GBC board determined a large part of the marketing problems it faced in early 1998 was attributable to a misunderstanding to the risks U.S. consumers associated with Guatemalan berries. To improve the understanding, the GBC early this year contracted industry writer Tad Thompson to produce this information piece, as well as public information releases to bring political, diplomatic, health, trade, and consumer officials and journalists up-to-date on the Guatemalan fruit export business.

Thompson will coordinate with FMI in developing this information.

Blackberries Were Never Associated with Cyclospora

Guatemalan blackberries are not carriers of the Cyclospora protozoa. This went on the record on July 28, 1997, when the FDA's Deputy Director of the Center for Food Safety and Applied Nutrition, Janice F. Oliver indicated to the Guatemala berry industry " to date (we have) had no epidemiological evidence that implicated blackberries in our current cyclosporiasis outbreaks and FDA would not object to resumption of fresh blackberry exports to the United States." There has been no indication since that time that blackberries are Cyclospora carriers.

Oliver continued: "Frozen raspberries and blackberries have not been implicated in outbreaks of cyclosporiasis and may be exported to the United States subject to normal FDA import and sampling procedures."

Despite this clearance, Guatemalan blackberries faced low prices early this year, unlike fruit from other origins. Despite what was widely regarded as Guatemala's superior quality, other fruit sold for $4-6 per-flat more.

Moving Ahead with High Level Commission

Top political and private sector organizations in Guatemala are working together as the *High Level Commission* to resolve the issues facing Guatemalan raspberry exporters. The serious trade problems facing berry exporters have negatively impacted many aspects of Guatemalan agriculture. Thus, five work groups are working on these objectives:

Investigation, Epidemiology & Environmental Work Group

Formulating and executing scientific investigation protocols, with support of international experts, to better understand the source and form of Cyclospora contamination. The group is also formulating a protocol budget plan.

Treatment Evaluations Work Group

Formulating and executing protocols evaluating the efficiency of diverse postharvest treatments to eliminate the presence of microorganisms harmful to humans. Options for these treatments include ozone, irradiation, and methyl bromide.

Inspection, Certification and Verification Work Group

Working to revise, correct, endorse and apply inspection procedures, certification and verification fulfillment from the farms and exporters' warehouses. The advisory council of the scientific group, PIPAA, is revising and approving the rules and instruments of the technical evaluations of farms and exporters' warehouses and apply the test to the system's users. The system must guarantee the certified farms and the exporters' warehouses are risk-free.

Image Rescue Work Group

Designing a strategy to rescue the lost image in the U.S. market and avoid that transcending from berries to other produce and markets. Relying on the results of the other work groups; especially on the credibility of the inspection and certification system. The goal is that the FDA will publicly recognize Guatemala has a very reliable control system.

Commercial Practices Work Group

Advising the berry industry on fulfilling sanitary and phytosanitary regulations within the commercial practices of the World Commerce Organization (WCO), Geneva, Switzerland. A permanent Guatemalan Ambassador at the WCO is valuable for Guatemala's globalization process.

A POSITIVE INTERNATIONAL FOOD SAFETY EXAMPLE FOR THE WORLD

(Continued from page 1)

country's berry interests in the U.S. The growers agreed to stringent Guatemalan national laws to assure that no berries are exported from Guatemala unless they have been grown, packed and shipped under HACCP conditions.

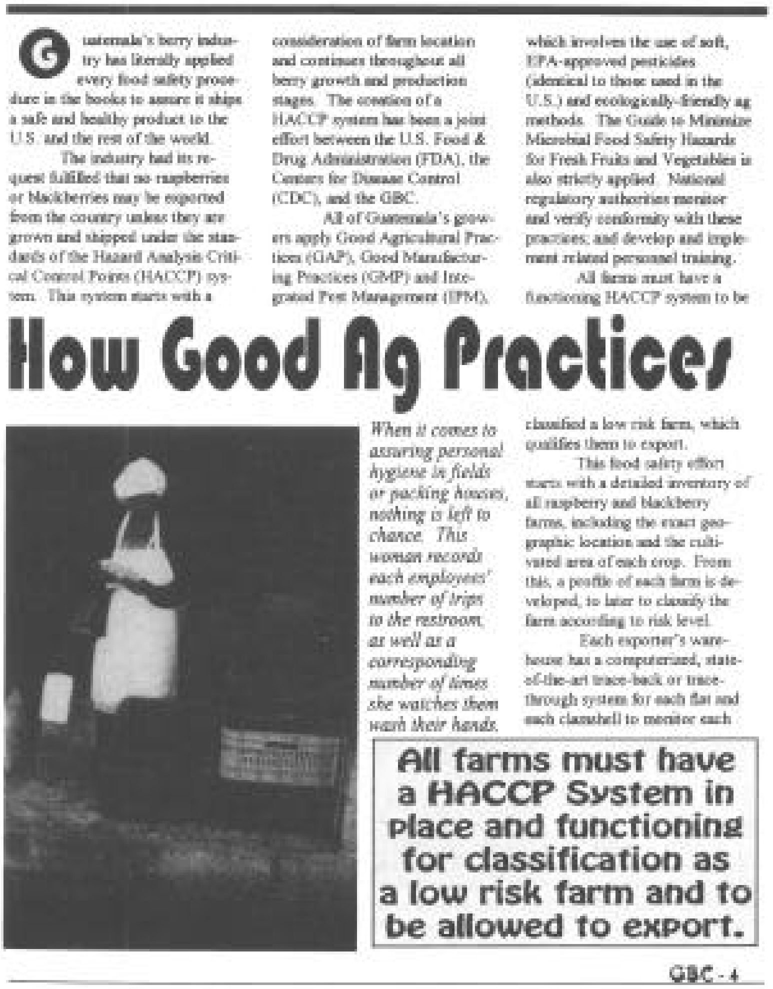
"...the most stringent standards worldwide."

To assure raspberries are never again considered a food safety risk, the Guatemalans have asked for, received, and faithfully implemented technical advice from cooperative international experts. These scientists not only came from groups like the FDA and CDC, but world-renowned consultants including horticulturist Dr. David Picha of Louisiana State University. A group of Guatemalan doctors have focused on studying Cyclospora in their country.

Guatemalan berry shipping procedures are highlighted by the HACCP System at Farm and Exporters' Level, but also include Good Agricultural Practices, Good Manufacturing Practices, and state-of-the-art "Trace-Through", or "Trace-Back" systems.

Making the most of a difficult situation, the Guatemalans are using this experience to ultimately establish the finest food safety reputation in the world.

Dr. John Farquhar, an FMI food scientist, said these food safety procedures "distinguish the berry industry as at least equal to the world's best shippers. There are none better, because the Guatemalans have implemented the most stringent standards worldwide on berries. They have the highest standards and guidelines."



How Good Ag Practices

Guatemala's berry industry has literally applied every food safety procedure in the books to assure it ships a safe and healthy product to the U.S. and the rest of the world.

The industry had its request fulfilled that no raspberries or blackberries may be exported from the country unless they are grown and shipped under the standards of the Hazard Analysis Critical Control Points (HACCP) system. This system starts with a consideration of farm location and continues throughout all berry growth and production stages. The creation of a HACCP system has been a joint effort between the U.S. Food & Drug Administration (FDA), the Centers for Disease Control (CDC), and the GBC.

All of Guatemala's growers apply Good Agricultural Practices (GAP), Good Manufacturing Practices (GMP) and Integrated Pest Management (IPM), which involves the use of soft, EPA-approved pesticides (identical to those used in the U.S.) and ecologically-friendly ag methods. The Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables is also strictly applied. National regulatory authorities monitor and verify conformity with these practices; and develop and implement related personnel training.

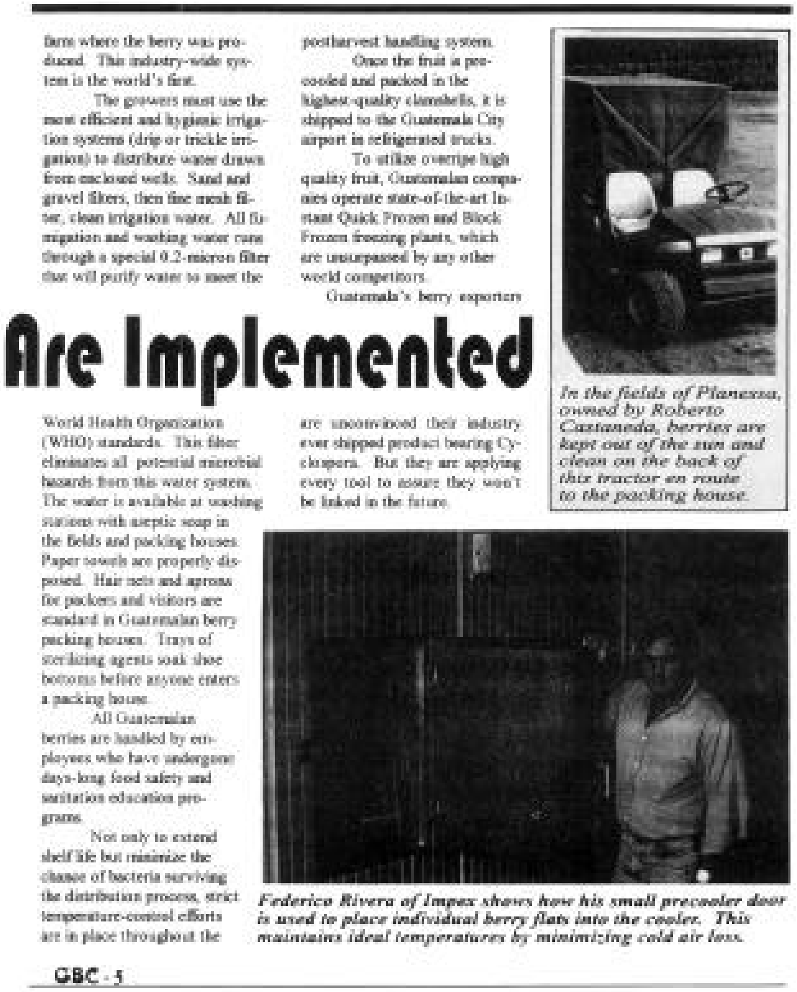
All farms must have a functioning HACCP system to be classified a low risk farm, which qualifies them to export.

This food safety effort starts with a detailed inventory of all raspberry and blackberry farms, including the exact geographic location and the cultivated area of each crop. From this, a profile of each farm is developed, to later to classify the farm according to risk level.

Each exporter's warehouse has a computerized, state-of-the-art trace-back or trace-through system for each flat and each clamshell to monitor each

When it comes to assuring personal hygiene in fields or packing houses, nothing is left to chance. This woman records each employees' number of trips to the restroom, as well as a corresponding number of times she watches them wash their hands.

All farms must have a HACCP System in place and functioning for classification as a low risk farm and to be allowed to export.



Are Implemented

farm where the berry was produced. This industry-wide system is the world's first.

The growers must use the most efficient and hygienic irrigation systems (drip or trickle irrigation) to distribute water drawn from enclosed wells. Sand and gravel filters, then fine mesh filter, clean irrigation water. All fumigation and washing water runs through a special 0.2-micron filter that will purify water to meet the World Health Organization (WHO) standards. This filter eliminates all potential microbial hazards from this water system. The water is available at washing stations with aseptic soap in the fields and packing houses. Paper towels are properly disposed. Hair nets and aprons for packers and visitors are standard in Guatemalan berry packing houses. Trays of sterilizing agents soak shoe bottoms before anyone enters a packing house.

All Guatemalan berries are handled by employees who have undergone days-long food safety and sanitation education programs.

Not only to extend shelf life but minimize the chance of bacteria surviving the distribution process, strict temperature-control efforts are in place throughout the postharvest handling system.

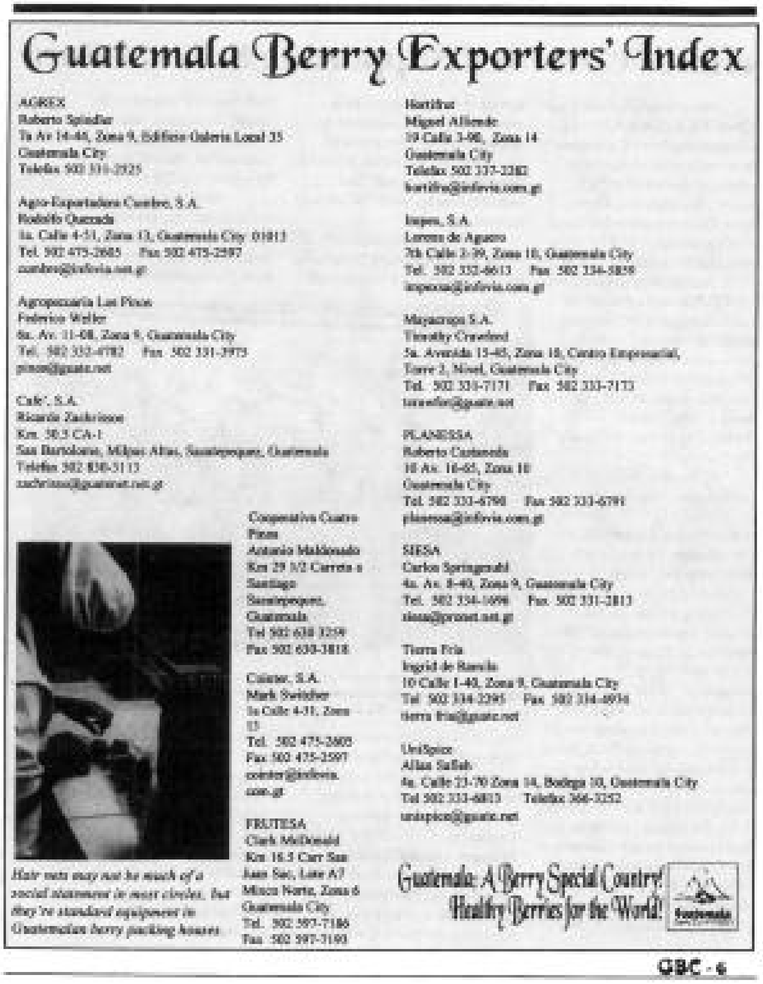
Once the fruit is precooled and packed in the highest-quality clamshells, it is shipped to the Guatemala City airport in refrigerated trucks.

To utilize overripe high quality fruit, Guatemalan companies operate state-of-the-art Instant Quick Frozen and Block Frozen freezing plants, which are unsurpassed by any other world competitors.

Guatemala's berry exporters are unconvinced their industry ever shipped product bearing Cyclospora. But they are applying every tool to assure they won't be linked in the future.

In the fields of Planessa, owned by Roberto Castaneda, berries are kept out of the sun and clean on the back of this tractor en route to the packing house.

Federico Rivera of Impex shows how his small precooler door is used to place individual berry flats into the cooler. This maintains ideal temperatures by minimizing cold air loss.



Guatemala Berry Exporters' Index

AGREX
Roberto Spindler
7a Av 14-44, Zona 9, Edificio Galeria Local 35
Guatemala City
Telefax 502 331-2525

Agro-Exportadora Cumbre, S.A.
Rodolfo Quezada
1a. Calle 4-51, Zona 13, Guatemala City 01013
Tel. 502 475-2605 Fax 502 475-2597
cumbre@infovia.net.gt

Agropecuaria Las Pinos
Federico Weller
8a. Av. 11-08, Zona 9, Guatemala City
Tel. 502 332-4782 Fax 502 331-3975
pinos@guate.net

Cafe', S.A.
Ricardo Zachrisson
Km. 50.5 CA-1
San Bartolome, Milpas Altas, Sacatepequez, Guatemala
Telefax 502 830-3113
zachrisso@guatenet.net.gt

Cooperativa Cuatro Pinos
Antonio Maldonado
Km 29 1/2 Carreta a Santiago
Sacatepequez, Guatemala
Tel 502 630 3259
Fax 502 630-3818

Cointer, S.A.
Mark Switcher
1a Calle 4-31, Zona 13
Tel. 502 475-2605
Fax 502 475-2597
cointer@infovia.com.gt

FRUTESA
Clark McDonald
Km 16.5 Carr San Juan Sac, Lote A7
Mixco Norte, Zona 6
Guatemala City
Tel. 502 597-7186
Fax 502 597-7190

Hair nets may not be much of a social statement in most circles, but they're standard equipment in Guatemalan berry packing houses.

Hortifrus
Miguel Allende
19 Calle 3-90, Zona 14
Guatemala City
Telefax 502 337-2282
hortifru@infovia.com.gt

Impex, S.A.
Lorena de Aguero
7th Calle 2-39, Zona 10, Guatemala City
Tel. 502 332-6613 Fax 502 334-5859
impexsa@infovia.com.gt

Mayacrops S.A.
Timothy Crawford
5a. Avenida 15-45, Zona 10, Centro Empresarial, Torre 2, Nivel, Guatemala City
Tel. 502 333-7171 Fax 502 333-7173
tcrawfor@guate.net

PLANESSA
Roberto Castaneda
10 Av. 16-65, Zona 10
Guatemala City
Tel. 502 333-6790 Fax 502 333-6791
planessa@infovia.com.gt

SIESA
Carlos Springmuhl
4a. Av. 8-40, Zona 9, Guatemala City
Tel. 502 334-1096 Fax 502 331-2813
siesa@pronet.net.gt

Tierra Fria
Ingrid de Rancila
10 Calle 1-40, Zona 9, Guatemala City
Tel 502 334-2295 Fax 502 334-6934
tierra fria@guate.net

UniSpice
Allan Saffah
4a. Calle 23-70 Zona 14, Bodega 10, Guatemala City
Tel 502 333-6813 Telefax 366-3252
unispice@guate.net

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Healthy Berries for the World!

GBC - 6

Senator Coverdell Supporting Safety Effort

United States Senator Paul D. Coverdell is closely following the Guatemalan berry/Cyclospora saga through close contact with Guatemalan Ambassador Pedro Lamport. But early last winter, Senator Coverdell got a first hand tour of the situation with Guatemalan President Alvaro Arzu, the U.S. Ambassador to Guatemala, Donald Planty, and a number of Guatemalan dignitaries, showing Guatemalan raspberry — and other — food safety procedures. The Guatemala Berry Commission led the tour as one of many efforts to build an international understanding of their leadership in food safety.

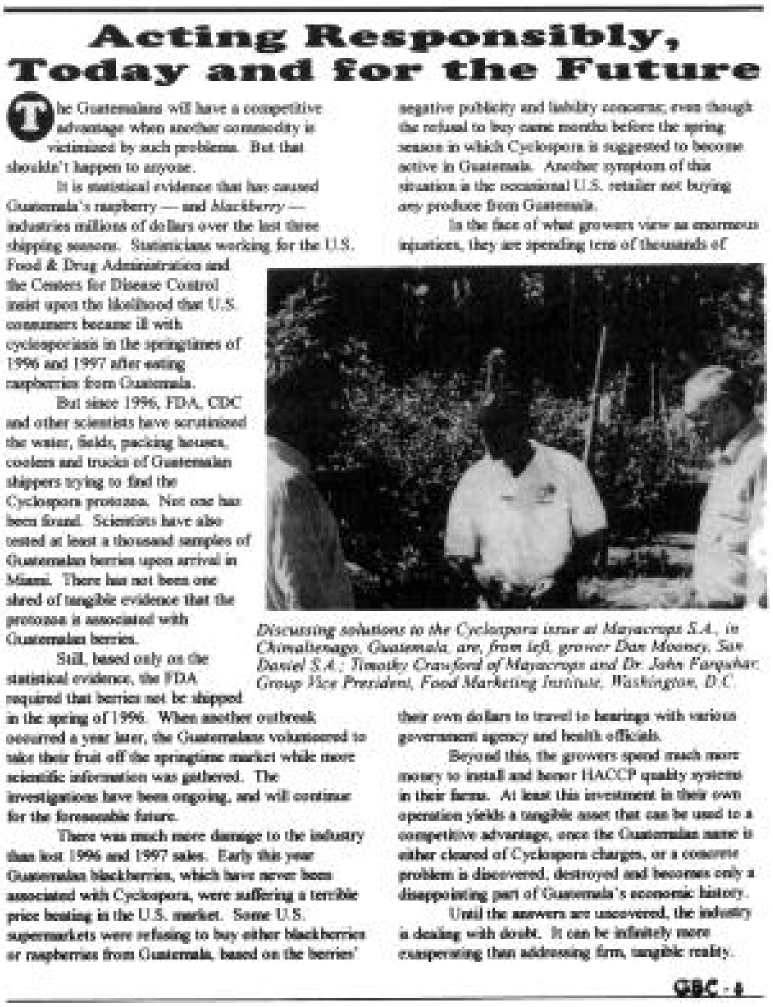
Of the tour, Senator Coverdell said: "Having returned from my third trip to Guatemala, I was heartened and impressed by the investments the producers have made in food safety infrastructure and their dedication to promoting growth for non-traditional export products. The production facilities we toured on our visit were highly sophisticated. While we enjoy a favorable trade relationship with Guatemala, which certainly we do not want to see jeopardized, there are still legitimate food safety concerns we have for American consumers we will have to address in a careful fashion. Knowing the stakes involved for the Guatemalan Berry Commission and Agexpront on this issue, I have encouraged assistance from our government through the FDA and CDC in solving the problems we have experienced. I am cognizant and respectful of the Guatemalans' assertions that the ramifications of this project's (nontraditional exports) success would be felt well beyond the farm."

Reviewing sanitary procedures at Planessa are, from left, GBC Vice President Joseph Daniel Mooney; Guatemalan President Alvaro Arzu; U.S. Senator Paul Coverdell and, in the dark shirt, GBC President Roberto Castaneda.

In addition to seeing Pacific Coast shrimp and sugar processing plants, the Senator from Georgia toured the produce packing and cooling facilities of Cooperativa Cuatro Pinos, and the berry farm and packing house of Planessa, which is owned by Roberto Castaneda. Cuatro Pinos' General Manager Antonio Maldonado showed the Senator Cuatro Pinos' Microbial and Pesticide Residue labs, as well as the very-clean conditions for packing and handling fresh fruit and vegetables for export. Castaneda, who is also President of the Guatemalan Berry Commission, showed each step Planessa's HACCP system.

All of the facilities toured by Coverdell operate with HACCP food safety standards. No Guatemalan berries are allowed to leave Guatemala unless they are produced under HACCP standards.

Also participating in the tour were Guatemalan Ministers of Economy, Health, Foreign Relations, and Agriculture. Other U.S. diplomats and Guatemalan agricultural leaders participated, including Dr. Robert Klein, Director of the CDC in Guatemala, who has been valuable to this process.



Acting Responsibly, Today and for the Future

The Guatemalans will have a competitive advantage when another commodity is victimized by such problems. But that shouldn't happen to anyone.

It is statistical evidence that has caused Guatemala's raspberry — and *blackberry* — industries millions of dollars over the last three shipping seasons. Statisticians working for the U.S. Food & Drug Administration and the Centers for Disease Control insist upon the likelihood that U.S. consumers became ill with cyclosporiasis in the springtimes of 1996 and 1997 after eating raspberries from Guatemala.

But since 1996, FDA, CDC and other scientists have scrutinized the water, fields, packing houses, coolers and trucks of Guatemalan shippers trying to find the Cyclospora protozoa. Not one has been found. Scientists have also tested at least a thousand samples of Guatemalan berries upon arrival in Miami. There has not been one shred of tangible evidence that the protozoa is associated with Guatemalan berries.

Discussing solutions to the Cyclospora issue at Mayacrops S.A., in Chimaltenago, Guatemala, are, from left, grower Dan Mooney, San Daniel S.A.; Timothy Crawford of Mayacrops and Dr. John Farquhar, Group Vice President, Food Marketing Institute, Washington, D.C.

Still, based only on the statistical evidence, the FDA required that berries not be shipped in the spring of 1996. When another outbreak occurred a year later, the Guatemalans volunteered to take their fruit off the springtime market while more scientific information was gathered. The investigations have been ongoing, and will continue for the foreseeable future.

There was much more damage to the industry than lost 1996 and 1997 sales. Early this year Guatemalan blackberries, which have never been associated with Cyclospora, were suffering a terrible price beating in the U.S. market. Some U.S. supermarkets were refusing to buy either blackberries or raspberries from Guatemala, based on the berries' negative publicity and liability concerns, even though the refusal to buy came months before the spring season in which Cyclospora is suggested to become active in Guatemala. Another symptom of this situation is the occasional U.S. retailer not buying *any* produce from Guatemala.

In the face of what growers view as enormous injustices, they are spending tens of thousands of their own dollars to travel to hearings with various government agency and health officials.

Beyond this, the growers spend much more money to install and honor HACCP quality systems in their farms. At least this investment in their own operation yields a tangible asset that can be used to a competitive advantage, once the Guatemalan name is either cleared of Cyclospora charges, or a concrete problem is discovered, destroyed and becomes only a disappointing part of Guatemala's economic history.

Until the answers are uncovered, the industry is dealing with doubt. It can be infinitely more exasperating than addressing firm, tangible reality.

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 8

MEMORANDUM

July 6, 1998

TO: PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
MEMBERSHIP LIAISONS

FROM: DON MULLINAX, Chief Investigator
STEPHANIE SMITH, PhD, Investigator
MARY MITSCHOW, Counsel
Permanent Subcommittee on Investigations

VIA: TIMOTHY J. SHEA, Chief Counsel/Staff Director
Permanent Subcommittee on Investigations

RE: PSI HEARING ON THE SAFETY OF FOOD IMPORTS: FROM THE FARM TO THE TABLE -- A CASE STUDY OF TAINTED IMPORTED FRUIT

* * * * * * *

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Attachment A: CDC Organizational Chart
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Attachment D: New England Journal of Medicine (1996 Outbreak of Cyclosporiasis)
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Attachment G: Risk Science Institute Article

I. INTRODUCTION

The Permanent Subcommittee on Investigations (PSI) will hold a hearing on July 9, 1998, at 9:30 a.m. in SD-342. The hearing is entitled: "The Safety of Food Imports: From the Farm to the Table -- A Case Study of Tainted Imported Fruit."

The second PSI food safety hearing will focus on a specific case study of an outbreak of *Cyclospora* infection associated with fresh raspberries imported from Guatemala.[1] Multistate outbreaks occurred in 1996 and 1997.

Cyclospora is a parasite composed of one cell, too small to be seen without a microscope.[2] The first know human cases of infection with this parasite were reported in medical literature in 1979.[3] Cases have been reported with increased frequency from various countries since the mid-1980's, in part because of the availability of better techniques for detecting the parasite in stool specimens.[4] Until 1996, most of the documented cases of cyclosporiasis in North America were in overseas travelers.[5] However, two significant outbreaks associated with imported fruit occurred in the United States, one in 1996 and another in 1997.

---

[1] In this document, the terms *Cyclospora* and cyclosporiasis are used. For clarification, *Cyclospora* is the parasite or pathogen and cyclosporiasis is the illness caused by *Cyclospora*.

[2] CDC Fact Sheet. *Cyclospora* Infection. October 29, 1997.

[3] Ibid.

In 1996, a large outbreak of cyclosporiasis occurred in the United States and Canada. There were at least 1,465 cases of cyclosporiasis reported by 20 states, the District of Columbia, and 2 Canadian provinces.[6] The Centers for Disease Control and Prevention's (CDC) investigation of these cases revealed that the 1996 outbreak was associated with the consumption of Guatemalan raspberries.[7] Of the 1,465 reported cases, 315 were associated with seven states whose Senators are Members of this Subcommittee -- Maine (2), Pennsylvania (29), Connecticut (38), Georgia (5), Illinois (60), New Jersey (103), and Ohio (78).[8]

After this 1996 outbreak the Food and Drug Administration (FDA) and the CDC worked with the Guatemalan Berry Commission to improve the practices for growing and handling raspberries in Guatemala. The Commission voluntarily improved water quality and sanitary conditions and established a farm classification system (with only farms in the best class permitted to export) in an attempt to minimize the possibility that *Cyclospora*-contaminated raspberries would be exported to the United States.[9] Because cyclosporiasis may be a seasonal disease, Guatemalan raspberries were imported without restriction in the fall of 1996, and no cases of cyclosporiasis attributed to eating Guatemalan raspberries were reported to CDC during this time period.[10]

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[4] CDC Fact Sheet. Cyclospora Infection. October 29, 1997.

[5] The New England Journal of Medicine. An Outbreak in 1996 of Cyclosporiasis Associated with Imported Raspberries. May 29, 1997. P. 1.

[6] Ibid.

[7] Ibid.

[8] Ibid.

[9] CDC Fact Sheet. Outbreaks of Cyclosporiasis in the United States. January 6, 1998.

[10] Ibid.

Despite the measures taken by the Berry Commission, another outbreak linked to fresh raspberries occurred in the United States and Canada in April and May 1997.[11] A total of 1,012 cases of cyclosporiasis were reported in 17 states, the District of Columbia and two Canadian provinces.[12] The evidence again was compelling that Guatemala was the major source of the implicated raspberries.[13]

On May 30, 1997, the Guatemalan Berry Commission announced its decision to voluntarily suspend exports of fresh raspberries to the United States.[14] After shipments were suspended, no further outbreaks of cyclosporiasis linked to raspberries were noted in the United States and Canada during the spring and summer of 1997.[15]

On November 20, 1997, Dr. Fred Shank of FDA's Center for Food Safety and Applied Nutrition notified Roberto Castaneda, President of the Guatemalan Berry Commission, that the FDA would not allow fresh Guatemalan raspberries entry into the United States during the period of March 15 through August 15, 1998.[16] Dr. Shank also informed Mr. Castaneda that this position might change if the source of *Cyclospora* contamination was determined and corrected or if intervention technologies were developed which would prevent cyclosporiasis in humans.[17]

On March 24, 1998, the Vice-Minister of Agriculture, Minister of Health, and President of the Guatemalan Berry Commission submitted a proposal entitled "Model Plan of Excellence for the Export of Raspberries" to the FDA.[18] The proposal requested that seven Guatemala farms be allowed to ship fresh raspberries to the U.S. during the period March 15 through August 15, 1998.[19] On May 19, 1998, however, the FDA notified Guatemala officials that the FDA would consider allowing shipment of fresh raspberries from only two farms when compliance with all aspects of the Model Plan for Excellence had been demonstrated and when certain conditions set out by FDA had been met.[20]

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[11] CDC Fact Sheet. Outbreaks of Cyclosporiasis in the United States. January 6, 1998.

[12] Synopsis: 1997 Raspberry-Associated Outbreak of Cyclosporiasis. June 16, 1998.

[13] CDC Fact Sheet. Outbreaks of Cyclosporiasis in the United States. January 6, 1998.

[14] Ibid.

[15] Ibid.

[16] Letter from Dr. Fred R. Shank to Roberto Castaneda, dated November 20, 1997.

[17] Ibid.

[18] Letter from Guatemala government officials to Janice Oliver. Deputy Director of FDA's Center for Food Safety and Applied Nutrition, dated March 24. 1998.

On June 5, 1998, the Vice-Minister of Agriculture notified Dr. Joseph Levitt of FDA's Center for Food Safety and Applied Nutrition that the owners of the two farms expressed their willingness to implement the improvements required in order to export raspberries throughout the year and were ready to be visited by the FDA.[21] The Vice-Minister also requested that a third farm be considered by the FDA to export fresh raspberries.[22]

On June 12, 1998, Dr. Levitt informed the Vice-Minister of Agriculture that if the third farm requesting approval to export fresh raspberries complied with the Model Plan for Excellence and met the specific conditions outlined in the FDA's May 19th letter, the farm would be allowed to export fresh raspberries.[23] Dr. Levitt also informed the Vice-Minister that the FDA was making arrangement to visit Guatemala during the week of June 22th.[24]

In mid-June 1998, Toronto health officials reported that 250 people in Canada had become ill with *Cyclospora* from tainted food eaten during May. The health officials identified that raspberries (not from North America) was the common factor in the outbreak.

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[19] Letter from Guatemala government officials to Janice Oliver, Deputy Director of FDA's Center for Food Safety and Applied Nutrition, dated March 24, 1998.

[20] Letter from Joseph A. Levitt, Director of FDA's Center for Food Safety and Applied Nutrition to Luis Alberto Castaneda, Guatemala's Vice-Minister of Agriculture, dated May 19, 1998.

[21] Letter from Guatemala's Vice-Minister of Agriculture to Joseph A. Levitt, Director of FDA's Center for Food Safety and Applied Nutrition, dated June 5, 1998.

[22] Ibid.

[23] Letter from Joseph A. Levitt, Director of FDA's Center for Food Safety and Applied Nutrition to Guatemala's Vice-Minister of Agriculture, dated June 12, 1998.

[24] Ibid.

The witnesses called for this hearing will describe (i) how Guatemala raspberries made their way from the berry farms to American dinner tables, (ii) how *Cyclospora* affected a consumer who consumed tainted raspberries, and (iii) how outbreaks of *Cyclospora* were identified and traced back to Guatemala. The witnesses are:

Dr. Stephanie A. Smith, who is a PSI investigator and food scientist, will give a detailed description of the raspberry production process and how raspberries are transported from the fields of Guatemala to the dinner tables of America.

Dr. Jeffrey A. Foran, who is a chemical toxicologist, will bring a unique perspective to the hearing -- a victim of *Cyclospora* and a scientist. Not only will he discuss the severe affects that *Cyclospora* had on him, but he will also discuss the importance of science and risk assessment in assessing the risks of human disease following exposure to pathogens.

Dr. Stephen M. Ostroff and Dr. Barbara L. Herwaldt are both from the CDC's National Center for Infectious Diseases. Dr. Ostroff, who is the Associate Director for Epidemiologic Science, will present CDC's oral testimony and Dr. Herwaldt, who is a Medical Epidemiologist in the Division of Parasitic Diseases, will be available to answer specific questions about the 1996 and 1997 *Cyclospora* outbreaks. These scientists will describe the government's procedures and processes for investigating and tracing outbreaks of foodborne illness to the source of contamination. Although the CDC is not the only, or even the primary, agency rsponsible for investigating foodborne illnesses, CDC officials work closely with all those entities involved in such investigations, including the state health departments and the federal regulatory agencies. The CDC plays a support role to all of those agencies, providing scientific expertise to interstate outbreaks of foodborne illnesses, and as such, the agency is familiar with the intergovernment effort to investigate these types of outbreaks.

II. BACKGROUND

A. U.S. Financial Assistance to Guatemala. According to press reports and other accounts in the mid-1980's, the U.S. Agency for International Development (USAID) initiated programs in Guatemala to cultivate non-traditional crops for export as alternatives to Guatemala's traditional crops of corn and beans grown for domestic consumption.[25] The implication of the press reports was that the United States has banned the importation of a crop that it paid to establish in a developing country, namely raspberries in Guatemala.

In preparation for this case study, PSI staff sought to independently verify the accuracy of these press reports. The most current results are as follows:

The press reports were confirmed, in part, during an interview of Bruce Brower by PSI staff. Mr. Brower is a group manager of Chemonics International, a company that subcontracted with USAID from 1986-1995 to promote the production of non-traditional agricultural exports (NTAEs) in Central America. USAID employed Chemonics to manage two programs -- PROEXAG and EXITOS -- which required Chemonics to provide plants, materials and training to Guatemalan farmers who in turn provided land, labor and pesticides. Mr. Brower told PSI staff that raspberries were among the alternative crops supported through the USAID program. Mr. Brower estimated that USAID provided Chemonics about $7.7 million from 1986 through 1995 for the Central American project and that "well under $1 million" was spent specifically on Guatemalan raspberries. In a subsequent discussion with PSI staff, Mr. Brower indicated that USAID spending on Guatemalan raspberries was more accurately estimated at $100,000.

In response to a PSI written inquiry (dated May 27, 1998) requesting, in part, "the level of U.S. financial assistance (by fiscal year) for the cultivation and development of the Guatemalan raspberry crop during the past 15 years," USAID responded in a June 12th letter that:

> "Raspberries were among the crops identified but their production costs pushed raspberry production to a producer group at an economic level greater than the target population for USAID programs. These producers worked on their own to develop their product market, i.e., without direct USAID program financial support."

When the author of the USAID letter was questioned about the response, she indicated that it was her understanding that raspberries were first funded in the mid-1980's by USAID through the PROEXAG program. It was also her understanding, however, that the cost of growing raspberries was excessive and prevented the USAID program from reaching the most impoverished Guatemalans. As a result, the raspberry program was terminated in the mid-1980's.

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[25] "Imports Swamp U.S. Food-Safety Efforts," NEW YORK TIMES, Sep. 29, 1997.

When confronted with the conflicting information supplied to the Subcommittee by Chemonics as well as the conflict in USAID's written response to the PSI's inquiry, the USAID official again reiterated that it was her understanding that U.S. funding for raspberry crops had ceased after a brief period in the mid-1980's.

In a subsequent phone call on the same day, the USAID official amended her earlier statements. She stated that USAID provided about $85,000 to support the Guatemalan raspberry crop from 1985 to 1994. She indicated that the money spent on raspberries comprised "less than 1 percent" of the PROEXAG and EXITOS budgets. On June 24, 1998, USAID informed PSI staff that the agency was totally re-drafting their response to the PSI inquiry and that a new response would be forwarded to the Subcommittee soon.

Raspberries and blackberries are not native to Guatemala.[26] Blackberries were first introduced and shown to successfully thrive in Guatemala during the late 1980's.[27] After the blackberry success, raspberries were introduced to Guatemala in the early 1990's.[28] The first large crop of Guatemalan raspberries exported to the United States was in 1995, with larger export yields the following two years.[29] In fact, the number of raspberry farms grew from 12 in the early 1990's to about 150 in 1998.[30]

B. Exports of Guatemala Raspberries. Raspberries are grown by individual farmers and then either exported directly to foreign markets or sold to Guatemalan companies for export. Guatemalan fresh raspberry exports have grown tremendously in the last few years. Both the number of producers and land under cultivation have increased. Total raspberry exports increased from 184,606 flats in the 1994-95 harvest year to 299,317 flats in the 1995-96 harvest year.[31] One flat of raspberries weighs approximately 5 kilograms.[32] In May 1995, seven Guatemalan exporters reported exporting approximately 55,951 flats of raspberries to the United States; in May 1996, eight Guatemalan exporters exported a total of 75,824 flats.[33]

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[26] FDA's Guatemalan Farm Trip Report. March 5-10, 1998. P. 2.

[27] Ibid.

[28] Ibid.

[29] Ibid.

[30] PSI staff interview with Bruce Brower (12 farms) and PSI staff telephone conversation with Roberto Rosenberg of Guatemalan Embassy (150 farms).

Although Guatemala exports raspberries to Europe, the U.S. receives 98 percent of Guatemala raspberry exports.[34] The proximity of the U.S. to Central America permits Guatemalan raspberries to enter the U.S. and reach their final destination within hours to several days after harvesting. This quick transit time suits the raspberries' storage requirements as they have a shelf-life of only 7 to 10 days once harvested.[35] Miami is the largest port of entry for U.S. raspberry imports (88 percent) from Guatemala followed by minimal imports to New York, Houston, Washington, D.C., and Los Angeles.[36] Raspberry exports from Guatemala occur year-round, but larger quantities are exported in October, November, May, and June. These quantities coincide with peak harvest seasons, and the low seasons for Chilean and California raspberries.

C. Raspberry Production Process. Berries were first introduced in Guatemala for export about 10 years ago. Over the last 4 to 5 years, Guatemala has become one of the world's leading sources of raspberries and blackberries. The industry has developed primarily in the central highland region of Guatemala. The climatic conditions are quite favorable for certain varieties of raspberries and the rich, volcanic soil facilitates rapid growth and excellent yields. Because of the climate and soil, raspberries can be manipulated through planting and pruning practices to come into harvest on demand given about 7 months lead time. The California season is generally late May through early October. So the export season for fresh Guatemalan raspberries is normally late October through May.[37]

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[31] CDC Foreign Trip Report -- Guatemala. December 20, 1996. P.2.

[32] Ibid. P.2.

[33] Ibid. P.2.

[34] Ibid. P.2. The dependence on exports to the United States magnified the economic impact on Guatemala when the United States decided to halt the imports of raspberries after the 1996 and 1997 outbreaks of *Cylospora*.

[35] Ibid. P.2.

[36] Ibid. P.2.

(1) Berry Development. For seedlings to become flowering plants requires approximately six months. Another six weeks is required for the raspberries to be ready for harvest. Raspberry plants are grown--typically, in hedgerows supported by canes and metal wires. The plants may or may not be tied to the wires individually. The fruit is grown 3 to 4 feet off the ground and, therefore, no direct contact occurs between the fruit and the soil. The plants are watered using drip irrigation. A drip irrigation system typically consists of a piece of plastic tubing running along the ground the length of the row. The underside of the tubing has small holes so the ground can be wet slowly over a long period of time. Thus, no direct contact occurs between the fruit and the water.

(2) Harvesting. Raspberries are harvested by hand, primarily by women. Ripe berries can be pulled from the plant very easily with bare hands leaving the cap on the vine. The pickers generally carry plastic trays strapped around their waists to keep their hands free. The plastic trays contain small plastic baskets into which the berries are placed. Once the baskets are full, the tray is taken to a packaging shelter so the berries can be sorted and packed. Raspberries are always picked dry and are NOT washed at any point prior to sale because they are very susceptible to mold.

(3) Sorting and Packing. Sorting is carried out in enclosed structures, again by woman. Typically, the structures have poured concrete floors and screened pass-through windows. By passing the trays brought from the fields through a window, tracking of dirt from the field into the packing shelter avoided. In addition, some farms use foot baths placed just outside the packing shelter door to clean shoe-bottoms before entering. Berries are generally sorted on large tables with smooth, white surfaces under a covered fluorescent light. Raspberries to be sold fresh are generally packed in half-pint plastic containers called clamshells. Clamshells are packed in cardboard flats. A flat holds 12 clamshells. Berries which are too ripe to be sold as fresh are typically put in five gallon plastic pails for freezing.

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[37] Picha, D.H. 1997. Background Information on Growing and Harvesting Practices. Presented at meeting in Washington DC, 7/23/97.

(4) Shipping. For shipping, the cardboard flats are packed in 3' x 3' x 4' E-containers. E-containers are styrofoam-insulated cardboard boxes. Ten flats fill an E-container. Gelpacks are added to keep the berries cold during international shipping. The E-containers are transported in refrigerated trucks from exporter warehouses to the airport. The trucks arrive at the airport between 11 p.m. and midnight. Upon arrival, the berries are held in cold storage at the cargo loading and storage area. Between 2 a.m. and 4 a.m., the berries are loaded onto either a cargo or passenger plane. All fresh raspberries from Guatemala are shipped by air to the U.S.

(5) Border Inspection. Miami, Florida is the principal port of entry for fresh Guatemalan raspberries, with approximately 88 percent of the berries passing through its airport. After arriving in Miami, the berries are unloaded from the planes and must pass through a USDA cargo clearance area. Each cargo clearance area contains an inspection table where produce and flowers are inspected. Here, E-containers are opened and the gelpacks are discarded. USDA inspectors (Animal and Plant Health Inspection Service) remove clamshells from the flats, open them, and dump the contents on the table. After inspection for insects (not food safety), the berries are placed back in their clamshells, replaced in their flats, and returned to their storage locations before being collected by the Miami-based importers.

(6) U.S. Distribution. Some Miami-based importers bring the raspberry flats to a blast cooler for rapid cooling following inspection. After 60 to 90 minutes of cooling at 34 degrees Fahrenheit, the berries are moved to coolers, or large refrigerated storage rooms, maintained between 34 and 38 degrees Fahrenheit where they remain until they are shipped to distributors. Raspberry flats are shipped to other distributors in one of two ways. If they are transported in a non-refrigerated truck they are repackaged into E-containers with several new gelpacks placed between the flats of the top layer. If they are shipped in a refrigerated truck, the flats are stacked on a pallet without gelpacks. Distributors fill and deliver orders for fresh raspberries placed by retail outlets and food service establishments. Upon receipt, fresh produce is stored briefly until displayed for sale or prepared for consumption.

D. *Cyclospora* -- the Parasite. *Cyclospora cayetanensis* is a protozoan coccidian parasite. A one-celled organism, it is related to other organisms such as *Toxoplasma* and *Cryptosporidium*. It is a prototypical emerging pathogen. *C. cayetanensis* is unusual in that it is not immediately infectious when excreted. Under optimal conditions, it matures in days to weeks, so direct person-to-person spread is very unlikely. An outbreak following a meal is probably not caused by the food handler. The organism appears to be seasonal, and in most places where it has been studied, it occurs in the spring or summer and causes little or no disease during the fall or winter. Infection has been reported throughout the world, and the key studies have been conducted in Peru and Nepal. Disease caused by *C. cayetanensis* is characterized by watery stools, nausea, weight loss, low-grade fever, fatigue, or any combination of these symptoms. The disease (which is easily treatable) can be quite protracted, and without treatment, relapse can occur. The mean incubation period of one week complicates the epidemiology; cases may not be recognized until two weeks after people have been exposed.[38]

E. Outbreaks of *Cyclospora* Infection

(1) 1996 Outbreaks. In 1996, a total of 1,465 cases of cyclosporiasis (the disease caused by the *Cyclospora* parasite) were reported by 20 states, the District of Columbia, and 2 Canadian provinces. Of these cases, 978 were laboratory confirmed and 725 were associated with 55 events that were held from May 3 through June 14, 1996. Raspberries were definitely served at 50 of the events and may have been served at four other events.[39]

Of the 1,465 cases, 725 were associated with a cluster and 740 were sporadic.[40] A cluster was defined as a group of two or more cases among persons who, during May 1 through August 31, 1996, shared at lease one meal or food item at an event (e.g., a luncheon or conference) and began to have at least one gastrointestinal symptom 12 hours to 14 days later. At least one case per cluster had to be laboratory-confirmed; clinical case definitions for probable cases varied. Persons who attended the events associated with cases of cyclosporiasis were interviewed about symptoms and their consumption of food and beverages at the event.[41]

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[38] Majkowski, J. 1997. Strategies for Rapid Response to Emerging Foodborne Microbial Hazards. Emerging Infectious Diseases. Volume 3, Number 4.

[39] The New England Journal of Medicine. An Outbreak in 1996 of Cycloporiasis Associated with Imported Raspberries. May 29, 1997. P. 1.

[40] Ibid. P. 2.

[41] Ibid.

Sporadic cases were not associated with identified clusters, were laboratory confirmed, were characterized by the development of gastrointestinal symptoms during May 1 through August 31, and occurred in persons who had not traveled outside the United States or Canada during the two weeks before the onset of symptoms.[42]

The CDC (along with officials from the FDA and state health departments) attempted to trace the sources of raspberries for the 54 events at which raspberries were or may have been served. The CDC was able to obtain well-documented data on the source for 29 events. This data showed that the raspberries served at 21 of the events definitely were from Guatemala and those served at 8 events could have originated in Guatemala.[43] Because exporters typically combined raspberries from multiple farms in a shipment, the CDC could identify only a group of contributing farms rather than one source farm.[44]

To identify the sources of implicated raspberries, the CDC obtained dates of purchase and shipment. The CDC used airway bill numbers supplied by importers to identify shipments and exporters and then farms that contributed to shipments. A well-documented tracing of the source was one in which each step from consumers back to farms was confirmed verbally and in writing (e.g., through copies of invoices). The CDC visited farms and exporters in Guatemala to investigate the ways in which raspberries were grown and handled. The CDC also investigated the way in which berries were inspected in the Miami airport.[45]

The CDC concluded that its investigation of a large outbreak of cyclosporiasis implicated Guatemalan raspberries.[46] The CDC could not assess the true magnitude of the outbreak; most cases were probably not diagnosed or unreported. For salmonellosis, which is a more familiar and easily diagnosed condition than cyclosporiasis, the number of cases reported to the CDC probably represents only 1 to 5 percent of all cases of infection in a year.[47] During routine testing for ova and parasites, stool specimens are not usually examined for *Cyclospora*, and many laboratories do not yet have the expertise to identify it. Experienced personnel in a few sites were instrumental in detecting the outbreak of cyclosporiasis at its inception in May 1996, and subsequent media coverage most likely facilitated the identification of cases.[48]

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[42] The New England Journal of Medicine. An Outbreak in 1996 of Cyclosporiasis Associated with Imported Raspberries. May 29, 1997. P.2.

[43] Ibid. P.5.

[44] Ibid. P.6.

[45] Ibid. P.4.

[46] Ibid. P.7.

The mode of contamination of the raspberries remains unclear. One hypothesis is that raspberries became contaminated through spraying with insecticides and fungicides that had been mixed with contaminated water. Although the CDC did not determine how water supplies on different farms could have become contaminated during the same period, many water supplies were vulnerable to contamination because, for example, they were suboptimally constructed or maintained wells near deep pit latrines or seepage pits. They may have been particularly vulnerable during the rainy season (e.g., from surface-water runoff), which is when the 1996 outbreak occurred.[49]

(2) 1997 Outbreaks. The CDC is still in the process of finalizing the results of the 1997 outbreak. The CDC, however, provided the Subcommittee with the following preliminary information. Between April 1 and May 26, 1997, a total of 1,012 cases of cyclosporiasis were reported in 17 states, the District of Columbia and two Canadian provinces.[50] These cases were linked to fresh Guatemalan raspberries.[51] The investigation of the outbreak focused on clusters of cases of cyclosporiasis that were associated with various events, such as wedding receptions. Specifically, 762 cases were associated with 41 cluster events and 250 cases were sporadic.[52]

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[47] The New England Journal of Medicine. An Outbreak in 1996 of Cyclosporiasis Associated with Imported Raspberries. May 29, 1997. P.7.

[48] Ibid.

[49] Ibid.

[50] Synopsis: 1997 Raspberry-Associated Outbreak of Cyclosporiasis. June 18, 1998.

[51] Ibid.

[52] Ibid.

For the 514 cases that were first reported and investigated, the CDC has published the following results. As of June 11, 1997, there were 21 clusters of cases of cyclosporiasis reported from eight states (California, Florida, Maryland, Nebraska, Nevada, New York, Rhode Island, and Texas) and one province in Canada (Ontario).[53] These clusters were associated with events (e.g., receptions, banquets, or time-place–related exposures that occurred during March 19 through May 25, 1997, and comprised approximately 140 laboratory-confirmed and 370 clinically-defined cases of cyclosporiasis.[54] In addition, four laboratory-confirmed sporadic cases were reported in the United States and Canada.

Fresh raspberries were served at 19 of the 21 events and were the only food in common to all 19 events, which occurred in April and May 1997.[55] At 6 of the 19 events, raspberries were the only type of berry served or were served separately from other berries; at 13 events, raspberries were included in mixtures of various types of berries.[56] Eating the food item that included raspberries was significantly associated with risk for illness for 7 of the 15 events for which epidemiologic data was available (including for three of the events at which raspberries were not served with other types of berries) and was associated with illness but not significantly for six events (i.e., all or nearly all ill persons ate the berry item that was served).[57]

Guatemala was identified as one of the possible sources of raspberries for all eight events for which traceback data was available (i.e., Guatemala was the source of at least one of the shipments of raspberries that could have been used) and as the only possible source for at least one of these events and perhaps for two others.[58]

(3) 1998 Canadian Outbreak. On June 11, 1998, Toronto Public Health issued a media release announcing that they were investigating seven outbreaks of *Cyclospora* infection related

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[53] CDC Morbidity and Mortality Weekly Report. June 13, 1997. P.1.

[54] Ibid.

[55] Ibid.

[56] Ibid.

[57] Ibid.

[58] Ibid.

to food eaten between May 7 and May 15.[59] The release also stated that more than 60 people had become ill with *Cyclospora* after attending various events in the City of Toronto.

On June 19, 1998, Toronto Public Health issued a media update stating that about 250 people had confirmed or suspected *Cyclospora* infection -- 160 of these were associated with 13 events, such as private parties and weddings.[60] The release also stated that the source of the outbreak was still unknown; however, a common item in all the events was imported raspberries. In addition, the media update stated that health officials were interviewing more than 700 people who attended the various events where people became ill.

On June 23, 1998, Toronto Public Health issued a second media update announcing that Dr. Barbara Yaffe, Associate Medical Officer of Health, had briefed the Board of Health on the *Cyclospora* outbreak.[61] Specifically, about 284 people had confirmed or suspected *Cyclospora* infection -- 170 of these were associated with 18 events, such as private parties and weddings.[62] The media update stated that raspberries eaten at several of the events investigated so far were believed to have originated in Guatemala.[63] The media update also stated that Toronto Public Health was working with local health units, Health Canada, the Ontario Ministry of Health, the Canadian Food Inspection Agency, and the CDC in Atlanta to find the source of the outbreak.

The Board of Health has asked the Public Health department to provide a detailed report on the outbreak when the current investigation is complete, along with recommendations for the labeling of fresh produce with the name of the country or place of origin. The Board also has asked the department to consider recommending a ban on the importation of Guatemalan raspberries, as is currently in place in the United States, if they are found to be the source of the current outbreak.

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[59] Toronto Public Health Media Release. June 11, 1998.

[60] Toronto Public Health Media Update. June 19, 1998.

[61] Toronto Public Health Media Update, June 23, 1998.

[62] Ibid.

[63] Ibid.

F. Investigating Outbreaks of Foodborne Illness

(1) Key Players and Responsibilities. Four federal agencies are charged with responding to outbreaks of foodborne illness: FDA, CDC, USDA, and EPA. All states, and many local governments, with widely varying expertise and resources, share responsibility for public health emergencies and work with the federal government in response to such outbreaks.[64] When an outbreak occurs, particularly one that occurs among several states, all of the relevant entities must work together to efficiently and effectively prevent deaths and minimize the number of illnesses. The better coordinated the response, the more quickly the outbreak will be contained.

Each of the four federal agencies has a potentially critical role when an outbreak occurs. CDC's primary responsibility is to assist state and local health departments in investigating outbreaks of illness and in identifying the cause of the outbreak.[65] The CDC serves as a scientific and analytical resource to these state regulatory agencies. The federal regulatory agencies, including FDA, USDA, and EPA also have responsibility for determining whether a product they regulate may be causing illness, and of halting the spread of illness by taking regulatory action against the suspect products, or wastes that have the potential to contaminate the air, land, or waters used to produce the food product.[66] The type of food affected determines which regulatory agency has primary jurisdiction: USDA regulates meat, poultry, and egg products; FDA regulates all other foods including shell eggs; and EPA regulates water and pesticides and manages organic and inorganic wastes used or disposed of on agricultural land. While each agency has defined areas of responsibility, the successful containment of many outbreaks of foodborne illness involves more than one agency.

The states and many local governments play a central role. Identification and investigations of foodborne illness often begin at the community or state level. States share with the federal government the legal responsibility for protecting the health of their residents.[67] Although foodborne outbreaks are sometimes local, most outbreaks implicate federal agency jurisdiction.[68] Illnesses cross state borders, and most foods or food ingredients are processed or produced in another state or by international trading partners.[69] Federal involvement is also necessary when contaminated food from a common source has been distributed to grocery stores, restaurants, and homes in more than one state.

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[64] Food Safety From Farm to Table: A National Food-Safety Initiative. Report to the President. May 1997.

[65] Ibid.

[66] Ibid.

In many outbreaks of foodborne illness, federal agencies work with state and local health authorities in their investigations and in implementation of control measures through consultation, diagnostic assistance, and by regulatory action against the products.[70] In some instances, on-site assistance is requested by the local and state authorities from the CDC to establish the cause of an outbreak, and from other agencies to help find the source of the problem.[71] For large or multistate outbreaks, federal agencies play a critical coordination role to ensure consistency of approach and implementation of needed control measures.

(2) The Investigative Process. Foodborne illnesses are investigated for two main reasons. The first is to identify and control an ongoing source by emergency action; product recall, restaurant closure, or other temporary but definitive solutions. The second reason is to learn how to prevent future similar outbreaks from occurring. In the long run this second purpose will have an even greater impact on public health than simply identifying and halting the outbreaks. Because all the answers are not available and existing regulations may not be sufficient to prevent outbreaks, the scientific investigation often requires a careful evaluation of the chain of production. This traceback is an integral part of the outbreak investigation. It is not a search for regulatory violations, but rather an effort to determine where and how contamination

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[67] Food Safety From Farm to Table: A National Food-Safety Initiative. Report to the President. May 1997.

[68] Ibid.

[69] Ibid.

[70] Ibid.

[71] Ibid.

occurred. Often, the contamination scenario reveals that a critical point has been lost. Therefore, epidemiologists must participate in traceback investigations.[72]

Because of the short shelf-life and broad distribution of many of the new foods responsible for infection, by the time the outbreak is recognized and investigated the relevant food may no longer be available for culture. Because the contamination may be restricted to a single production lot, blind sampling of similar foods that does not include the implicated lot can give a false sense of security. Good epidemiologic information pointing to contamination of a specific food or production lot should guide the microbiologic sampling and the interpretation of the results. Available methods may be insufficient to detect low-level contamination, even of well-established pathogens.[73]

Public health officials rely on epidemiology to find the source of outbreaks of foodborne illness. Many times, when people are diagnosed with a foodborne illness, their doctor or in most cases, the laboratory that detects a pathogenic organism in a fecal sample reports the incident to the local county health department. That department, in turn, reports cases periodically to the state department of health. States collect those local data and send reports to the CDC, which updates a national surveillance database.[74]

Until recently, officials at the CDC felt that the data from states did not contain enough detail to present an accurate picture of the scope or causes of foodborne illness. Consequently, in July 1995, the CDC, USDA, and FDA began a cooperative active surveillance project for foodborne disease in targeted locations in the United States. That project initially was called the Sentinel Site Study, and more recently is known as FoodNet.[75]

The purpose of FoodNet is to establish baseline data on the incidence rate of foodborne illnesses caused by seven foodborne bacterial pathogens: *E. coli 0157:H7*,

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[72] Emerging Infectious Diseases. Emerging Foodborne Diseases: An Evolving Public Health Challenge. Robert V. Tauxe. Volume 3, Number 4. October-December 1997. P. 9.

[73] Ibid.

[74] CRS Issue Brief. Food Safety Issues in the 105th Congress. March 30, 1998. P. 7.

[75] Ibid. P.7.

Campylobacter, *Listeria monocytogenes*, *Vibrio vulnificus*, *Yersinia*, *Shigella*, and *Salmonella*.[76] The project has three parts:

- Part 1, a laboratory-based surveillance, collects data weekly from medical laboratories to record the number of intestinal bacterial pathogens isolated from stool cultures and to confirm cases of each illness-causing pathogen in a given population;
- Part 2, population-based surveys, collects data to determine the incidence of diarrhea symptoms, and the proportion of people seeking medical attention from doctors;
- Part 3, uses the cases identified in part 1 to further determine what has happened.[77]

Where possible, the project determines what percentage of illness is due to specific foods. The final data on rates of illness will serve to tell policy makers which pathogens cause human illness. Those data will also establish baseline levels of illness with which future studies can be compared to see if food safety regulatory activities lower the incidence of illness.

III. CDC FISCAL YEAR 1999 BUDGET REQUEST

The CDC is the lead federal agency responsible for promoting health and quality of life by preventing and controlling disease, injury, and disability. CDC accomplishes its mission by working with partners throughout the nation and the world to monitor health, detect and investigate health problems, conduct research to enhance prevention, develop and advocate sound health policies, implement prevention strategies, promote healthy behaviors, foster safe and healthy environments, and provide public health leadership and training.[78]

The CDC's FY 99 budget justification included a request for an increase of $5 million and 10 FTEs (full-time equivalents) to implement an interagency food safety initiative, surveillance, and early warning system.

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[76] CRS Issue Brief. Food Safety Issues in the 105th Congress. March 30, 1998. P.7

[77] Ibid. P.8.

[78] CDC's Fiscal Year 1999 Justification of Estimates for Appropriations Committees. P.164.

Centers for Disease Control and Prevention[79]
Infectious Diseases Activity Functions

	1997 Actual	1998 Appropriation	1999 Estimate	Increase or Decrease
Emerging Infections	$44,820,000	$59,082,000	$79,082,000	$20,000,000
Hantavirus	7,500,000	7,500,000	7,500,000	-0-
Lyme Disease	5,389,391	7,884,391	7,884,391	-0-
Foodborne Disease	**4,500,000**	**14,500,000**	**19,500,000**	**5,000,000**
Waterborne Diseases	300,000	300,000	300,000	-0-
Other Infectious Diseases	25,948,609	25,948,609	24,759,609	(1,189,000)
Total	$87,720,000	$115,215,000	$139,026,000	$23,811,000

Disease-causing microorganisms (pathogens) continue to threaten public health as new organisms emerge as foodborne threats, and well-known organisms acquire greater potency. According to the CDC, this $5 million increase will enable CDC to implement the following activities as part of the Interagency Food Safety Initiative: The National Early Warning System will increase federal support to state health departments to detect foodborne diseases by increasing the number of scientists available to investigate foodborne outbreaks and by enhancing laboratory-based surveillance of important foodborne pathogens through improved diagnostic reagent availability, diagnostic and subtyping development, standardization, and training. It will improve the quality and scope of foodborne disease surveillance in the 8 FoodNet sites and in other state health departments through enhanced staffing, training, laboratory capacity/infrastructure, and coordination. And it will also link federal and state public health laboratories with sophisticated computer technology that will enhance communications and data sharing, including the digitized fingerprints of foodborne pathogens.[80] The President's fiscal year 1999 budget justified this food safety initiative in this way:

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[79] CDC's Fiscal Year 1999 Justification of Estimates for Appropriations Committees. P. 112.

> "Ensuring the safety of the food supply is one of government's most enduring and important functions. In responding to new technologies that enable food producers to grow, process, and market a growing variety of food products, the private sector and federal, state and local governments face many challenges to maintaining and improving the safety of the Nation's food supply. Disease-causing microorganisms continue to threaten public health as new organisms emerge as foodborne threats, and well-known organisms acquire greater potency. This increase will enable CDC to expand the National Early Warning System, make improvements to the quality and scope of foodborne disease surveillance, and enhance links between federal and state public health laboratories with sophisticated computer technology that will enhance comunications and data sharing."[81]

The President's budget justification also provided that initially, the success of efforts to rebuild our nation's epidemiologic and laboratory capacity will largely be measured by an improved public health infrastructure, rather than reductions in disease. For many infectious disease programs, including CDC's food safety activities, improvements in our ability to recognize and track these diseases and improved "early warning" surveillance systems will result in an increase in the number of reported cases and outbreaks before there is a downward trend resulting from effective prevention programs.[82]

CDC's National Center for Infectious Diseases recognizes that the first step in re-establishing surveillance is to build and maintain our nation's epidemiologic and laboratory capacity. Epidemiologic and laboratory capacity is the ability to recognize, respond to, and monitor infectious diseases.[83]

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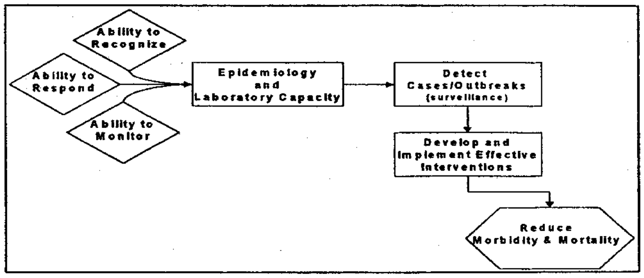
[80] CDC's Fiscal Year 1999 Justification of Estimates for Appropriations Committees. P. 109.

[81] Ibid. P. 57 and 58.

[82] Ibid. P.170.

[83] Ibid. P.170.

Model for Prevention and Control of Infectious Disease


Ability to Recognize
Ability to Respond
Ability to Monitor
Epidemiology and Laboratory Capacity
Detect Cases/Outbreaks (surveillance)
Develop and Implement Effective Interventions
Reduce Morbidity & Mortality

The President's budget justification that it means, at a minimum, supporting state and local health departments' efforts to build their infrastructures by hiring and training epidemiologists and laboratorians, supporting the development of new and improved diagnostic tests and new disease reporting systems, and equipping public health laboratories with state of the art technology. As illustrated above, with adequate epidemiologic and laboratory capacity, the steps necessary to reach the eventual goal of reducing morbidity and mortality -- detection of cases/outbreaks, as well as the development and implementation of effective interventions -- can be achieved.[84]

IV. GUATEMALA INITIATIVES. After the Guatemalan raspberries were implicated in the 1996 and 1997 outbreaks of *Cyclospora*, Guatemala began implementing several initiatives to ensure that Guatemala's agricultural products meet the highest standards of quality.

A. High Level Commission for Food Safety. Guatemala created a High Level Commission for Food Safety. The Commission is comprised of the Ministries of Agriculture, Health and Economy in coordination with the Non-Traditional Products Exporters Association. The Commission created five working groups -- Research, Epidemiology and Environment; Treatments Evaluation; Inspection, Certification and Verification; Commercial Promotion; and Commercial Practices. Guatemala also implemented a Sanitary and Quality Assurance System

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[84] CDC's Fiscal Year 1999 Justification of Estimates for Appropriations Committees. P.171.

Program (S&Q), that includes Hazard Analysis of Critical Control Points (HACCP) standards and FDA's future Good Agricultural Practices/Good Manufacturing Practices (GAP/GMP) voluntary guidance for fruit and vegetables.

B. Model Plan of Excellence for the Export of Raspberries (MPE). Guatemala also created the MPE which builds on the S&Q program and adds additional stringent standards to the production, processing, handling, and shipping of raspberries.

On March 24, 1998, Guatemala government officials submitted a proposal ("Model Plan of Excellence for the Export of Raspberries") to the FDA which requested that a limited number of Guatemalan farms be allowed to export fresh raspberries to the United States from March 15 through August 15, 1998. The plan was based on the knowledge and experience gained by Guatemala during the last two years regarding food safety procedures.

The objective of the MPE is to assure only safe raspberries are produced in Guatemala and exported to the United States. The MPE includes the implementation of Good Management Practices in farms and exporter plants and monitoring system during the picking, classification, packaging and transportation of the fruit. All these activities will be supervised directly by an inspector of the Integral Program of Agricultural and Environmental Protection (PIPAA).

The first activity in the design of the MPE was the selection of the farms to participate in it among the ones classified as "low risk farms" carried out by PIPAA. For this selection, PIPAA considered the infrastructure conditions, good agriculture and manufacturing practices, records management, and water quality. The framework of the MPE is fourfold -- quality assurance, training on good hygienic practices, control origin of fruit, and trace-through.

Guatemala also developed a regulation of the sanitary control system for production farms and packaging plants of raspberries and blackberries. The objective of the regulation is to regulate the production and commercial activity of raspberries and blackberries to guarantee the wholesomeness of the product. Guatemala also developed a "Guide of Minimum Requirements for Production and Packaging Units of Raspberries and Blackberries". The primary objective of this guide is to establish a baseline for the implementation of a system of Good Manufacturing Practices (GMP) and the use of HACCP in production and packaging units.

On May 19, 1998, the FDA responded to Guatemala's request that a limited number of Guatemalan farms be allowed to begin exporting raspberries to the United States.[85] Specifically, FDA's stated, in part, that:

> "We are aware of the imprecision of the scientific data regarding the source, biology, and virulence of *Cyclospora*. In the absence of such precise information, FDA cannot recommend with certainty measures that will prevent the contamination of fresh raspberries by this parasite. However, current scientific information is consistent with viewing *Cyclospora* as a waterborne fecal-oral contaminant. We, therefore, have reviewed your proposal in light of the operating assumption that *Cyclospora* is a waterborne organism that may be transmitted by water or humans via the fecal-oral route."

While the FDA response acknowledged that the Guatemalan berry industry had made improvements in water quality, sanitation, and employee hygiene at individual farms, the FDA specified that it did not have sufficient information to confirm that adequate interventions had been implemented for all of the farms identified in the proposal. The FDA, however, did agree to consider allowing shipment of fresh raspberries from two of the proposed farms when compliance with all aspects of the MPE had been demonstrated and when other specific conditions specified by the FDA had been met. The specific conditions include:

- Biological filters (0.5 micron size) must be installed for all water used for fumigation, cleaning and sanitation. The filters must be subjected to a testing protocol that would detect leaks or any other factor that would reduce filter efficiency and effectiveness. Any filter that fails the testing or later leaks or loses its effectiveness or efficiency must be immediately replaced.

- Assurance that prior to the installation of filters, water has not been used directly on fresh raspberries destined for export to the U.S.

- Integral Program of Agricultural and Environmental Protection (PIPAA) will reinspect the farms prior to harvesting fresh raspberries for export to the U.S., and will collect water samples after filtration for microbial analysis.

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[85] Letter from Joseph A. Levitt, FDA's Director of Food Safety and Applied Nutrition to Luis Alberto Castaneda, Guatemala's Vice Minister of Agriculture, dated May 19, 1998.

- Adequate supervision of farm workers to assure proper attire and appropriate employee sanitation practices, including adequate hand washing prior to picking, selection, and packing of fresh raspberries. Supervisors must have received proper training and be qualified to carry out their responsibilities.

- Assurance that PIPAA inspectors on farms and in plants have received proper training and are qualified to carry out their responsibilities.

- Assurance of adequate and properly used toilet facilities and supplies, and supervision of traffic into the selection area.

- The implementation of a surveillance program to ensure that workers are not asymptomatic or symptomatic for diarrheal disease as described in the "Protocol for the Epidemiological Surveillance of Risk Factors on Workers of Berry Producing Farms."

- Assurance that the flats of fresh raspberries leaving the farms will not be tampered with and will arrive intact as the exporters' warehouse and at the cargo loading and storage area in Guatemala City.

- A comprehensive monitoring program with checklist providing documentation that each of the farms has instituted all of the control practices listed above, and that there is a schedule of PIPAA inspections to assure that the controls remain in place throughout the growing and shipping season.

The FDA informed Guatemala that after the intervention strategies had been implemented, FDA would visit the two farms. Once all controls and operations are in place, FDA agreed to allow the shipment of fresh raspberries from the two farms to the U.S.

On June 5, 1998, the Vice-Minister of Agriculture notified Dr. Joseph Levitt of FDA's Center for Food Safety and Applied Nutrition that the owners of the two farms expressed their willingness to implement the improvements required in order to export raspberries throughout the year and were ready to be visited by the FDA.[86] The Vice-Minister also requested that a third farm be considered by the FDA to export fresh raspberries.[87] On June 12, 1998, Dr. Levitt informed the Vice-Minister of Agriculture that if the third farm requesting approval to export fresh raspberries complied with the Model Plan for Excellence and met the specific conditions outlined in the FDA's May 19th letter, the farm would be allowed to export fresh raspberries.[88] Dr. Levitt also informed the Vice-Minister that the FDA was making arrangement to visit Guatemala during the week of June 22th.[89]

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[86] Letter from Guatemala's Vice-Minister of Agriculture to Joseph A. Levitt, Director of FDA's Center for Food Safety and Applied Nutrition, dated June 5, 1998.

[87] Ibid.

IV. WITNESSES

A. Dr. Stephanie A. Smith. Dr. Smith's testimony will include a detailed description of the raspberry production process and how raspberries are transported from the fields of Guatemala to the dinner tables of American consumers. Dr. Smith's testimony will be based on her first-hand observations of raspberry farms and packing facilities in Guatemala as well as supplemented by reports prepared by various government agencies.

B. Dr. Jeffrey A. Foran. Dr. Foran, is a chemical toxicologist at the International Life Sciences Institute (ILSI) in Washington, D.C. ILSI a nonprofit, worldwide foundation that advances the understanding of scientific issues relating to nutrition, food safety, toxicology, and the environment. By bringing together scientists from academia, government, industry, and the public sector, ILSI works to develop a balanced approach to solving problems with broad implications for the well-being of the general public.

Dr. Foran will bring a unique perspective to the hearing -- a victim of *Cyclospora* and a scientist. Not only will he be able to discuss the severe affects that *Cyclopsora* had on him, but he will also be able to discuss the importance of science and risk assessment in assessing the risks of human disease following exposure to pathogens.

Dr. Foran contacted *Cyclospora* after eating raspberries at a buffet luncheon attended by members of his office. At least 11 other staff members contacted *Cyclospora*. Dr. Foran will be able to give the graphic details of the severity of the disease including how he lost about 12 pounds in a two-week period.

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[88] Letter from Joseph A. Levitt, Director of FDA's Center for Food Safety and Applied Nutrition to Luis Alberto Castaneda, Guatemala's Vice-Minister of Agriculture, dated June 12, 1998.

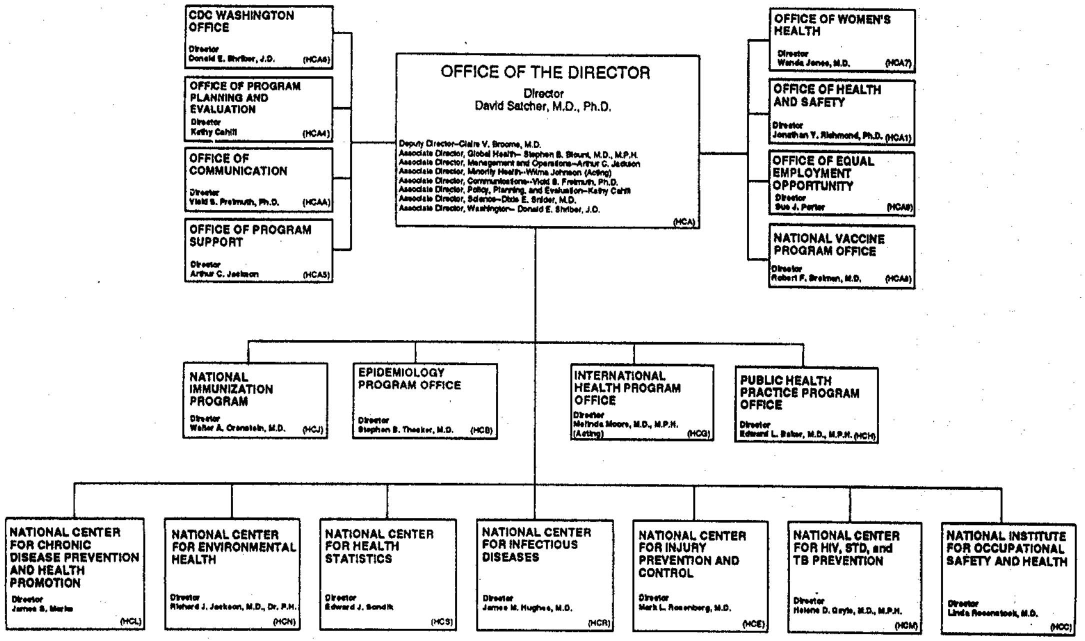
[89] Ibid.

C. Dr. Stephen M. Ostroff & Dr. Barbara L. Herwaldt. Dr. Ostroff and Dr. Herwaldt both work at the CDC's National Center for Infectious Diseases. Dr. Ostroff is the Associate Director for Epidemiologic Science and Dr. Herwaldt is a Medical Epidemiologist in the Division of Parasitic Diseases. Dr. Ostroff will describe the government's procedures and processes for investigating and tracing outbreaks of foodborne illness to the source of contamination in general terms. Dr. Herwaldt will respond to questions on the specific investigations and tracebacks of the 1996 and 1997 cyclosporiasis outbreaks associated with Guatemalan raspberries.

ATTACHMENT A

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE

CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC)


CDC WASHINGTON OFFICE
Director
Donald E. Shriber, J.D. (HCA6)
OFFICE OF PROGRAM PLANNING AND EVALUATION
Director
Kathy Cahill (HCA4)
OFFICE OF COMMUNICATION
Director
Vicki S. Freimuth, Ph.D. (HCAA)
OFFICE OF PROGRAM SUPPORT
Director
Arthur C. Jackson (HCA5)
OFFICE OF THE DIRECTOR
Director
David Satcher, M.D., Ph.D.
Deputy Director–Claire V. Broome, M.D.
Associate Director, Global Health– Stephen B. Blount, M.D., M.P.H.
Associate Director, Management and Operations–Arthur C. Jackson
Associate Director, Minority Health–Wilma Johnson (Acting)
Associate Director, Communications–Vicki S. Freimuth, Ph.D.
Associate Director, Policy, Planning, and Evaluation–Kathy Cahill
Associate Director, Science–Dixie E. Snider, M.D.
Associate Director, Washington– Donald E. Shriber, J.D.
(HCA)
OFFICE OF WOMEN'S HEALTH
Director
Wanda Jones, M.D. (HCA7)
OFFICE OF HEALTH AND SAFETY
Director
Jonathan Y. Richmond, Ph.D. (HCA1)
OFFICE OF EQUAL EMPLOYMENT OPPORTUNITY
Director
Sue J. Porter (HCA9)
NATIONAL VACCINE PROGRAM OFFICE
Director
Robert F. Breiman, M.D. (HCA8)
NATIONAL IMMUNIZATION PROGRAM
Director
Walter A. Orenstein, M.D. (HCJ)
EPIDEMIOLOGY PROGRAM OFFICE
Director
Stephen B. Thacker, M.D. (HCB)
INTERNATIONAL HEALTH PROGRAM OFFICE
Director
Melinda Moore, M.D., M.P.H. (Acting) (HCG)
PUBLIC HEALTH PRACTICE PROGRAM OFFICE
Director
Edward L. Baker, M.D., M.P.H. (HCH)
NATIONAL CENTER FOR CHRONIC DISEASE PREVENTION AND HEALTH PROMOTION
Director
James S. Marks (HCL)
NATIONAL CENTER FOR ENVIRONMENTAL HEALTH
Director
Richard J. Jackson, M.D., Dr. P.H. (HCN)
NATIONAL CENTER FOR HEALTH STATISTICS
Director
Edward J. Sondik (HCS)
NATIONAL CENTER FOR INFECTIOUS DISEASES
Director
James M. Hughes, M.D. (HCR)
NATIONAL CENTER FOR INJURY PREVENTION AND CONTROL
Director
Mark L. Rosenberg, M.D. (HCE)
NATIONAL CENTER FOR HIV, STD, and TB PREVENTION
Director
Helene D. Gayle, M.D., M.P.H. (HCM)
NATIONAL INSTITUTE FOR OCCUPATIONAL SAFETY AND HEALTH
Director
Linda Rosenstock, M.D. (HCC)

ATTACHMENT B

Cyclospora (SIGH-clo-SPORE-uh) Infection

What is *Cyclospora*?

Cyclospora cayetanensis (SIGH-clo-SPORE-uh KYE-uh-tuh-NEN-sis) is a parasite composed of one cell, too small to be seen without a microscope. The first known human cases of *Cyclospora* infection were reported in 1979. Cases began being reported more often in the mid-1980s.

How is *Cyclospora* spread?

Cyclospora is spread by people ingesting something, for example, water or food, that was contaminated with infected stool. For example, in 1996, a large outbreak of *Cyclospora* infection in the United States and Canada was caused by imported raspberries. *Cyclospora* needs time (days or weeks) after being passed in a bowel movement to become infectious. Therefore, it is unlikely that *Cyclospora* is passed directly from one person to another. It is unknown whether animals can be infected and pass infection to people.

Who is at risk for infection?

People of all ages are at risk for infection. In the past, *Cyclospora* infection was usually found in people who lived or traveled in developing countries, but people can be infected worldwide. In the United States, infection is more common during spring and summer.

What are the symptoms of infection?

Cyclospora infects the small intestine (bowel) and usually causes watery diarrhea, with frequent, sometimes explosive, bowel movements. Other symptoms can include loss of appetite, substantial loss of weight, bloating, increased gas, stomach cramps, nausea, vomiting, muscle aches, low-grade fever, and fatigue. Some people who are infected with *Cyclospora* do not have any symptoms.

How soon after infection will symptoms begin?

The time between becoming infected and becoming sick is usually about 1 week.

How long will symptoms last?

If not treated, the illness may last from a few days to a month or longer. Symptoms may seem to go away and then return one or more times (relapse).

What should I do if I think I may be infected?

See your health care provider.

How is *Cyclospora* infection diagnosed?

Identification of this parasite in stool requires special laboratory tests that are not routinely done. Therefore, your health care provider should specifically request testing for *Cyclospora*. Because *Cyclospora* can be difficult to diagnose, you may be asked to submit several stool specimens over several days. Your health care provider may have your stool checked for other organisms that can cause similar symptoms.

How is infection treated?

The recommended treatment for infection with *Cyclospora* is a combination of two antibiotics, trimethoprim-sulfamethoxazole, also known as Bactrim*, Septra*, or Cotrim*. People who have diarrhea should rest and drink plenty of fluids. They should seek their health care provider's advice before taking medicine to slow their diarrhea.

I am allergic to sulfa drugs; is there another drug I can take?

No alternative drugs have been identified yet for people who are sensitive to sulfa drugs. See your health care provider for other treatment recommendations.

How is infection prevented?

Avoiding water or food that may be contaminated with stool may help prevent *Cyclospora* infection. People who have previously been infected with *Cyclospora* can become infected again.

For more information:

1. CDC. Update: Outbreaks of *Cyclospora cayetanensis* infection - United States and Canada, 1996. MMWR 1996;45:611-2.
2. Hoge CW, et al. Placebo-controlled trial of co-trimoxazole for cyclospora infection among travellers and foreign residents in Nepal. Lancet 1995;345:691-3.
3. Hoge CW, et al. Epidemiology of diarrhoeal illness associated with coccidian-like organisms among travellers and foreign residents in Nepal. Lancet 1993;341:1175-9.
4. Huang P, et al. The first reported outbreak of diarrheal illness associated with *Cyclospora* in the United States. Ann Intern Med 1995;123:409-14.
5. Ortega YR, et al. Cyclospora species - a new protozoan pathogen of humans. N Engl J Med 1993;328:1308-12.
6. Soave R. *Cyclospora*: an overview. Clin Infect Dis 1996;23:429-37.

*** Use of trade names is for identification only and does not imply endorsement by the Public Health Service or by the U.S. Department of Health and Human Services.**

This fact sheet is for information only and is not meant to be used for self-diagnosis or as a substitute for consultation with a health care provider. If you have any questions about the disease described above or think that you may have a parasitic infection, consult a health care provider.

National Center for Infectious Diseases
Centers for Disease Control and Prevention
Atlanta, GA

Updated: 10/29/97 13:59:32
URL: http://www.cdc.gov/ncidod/diseases/cyclo/cyclogen.htm

Cyclospora: Information For Health Care Providers

What is *Cyclospora*?

Cyclospora cayetanensis is a unicellular parasite previously known as cyanobacterium-like or coccidia-like body (CLB). The first known human cases of infection with this parasite were reported in the medical literature in 1979. Cases have been reported with increased frequency from various countries since the mid 1980s, in part because of the availability of better techniques for detecting the parasite in stool specimens.

How is *Cyclospora* transmitted?

Infected persons excrete the oocyst stage of *Cyclospora* in their feces. Oocysts do not become infectious (i.e., sporulate) until days to weeks after excretion. Therefore, transmission of *Cyclospora* directly from an infected person to someone else is unlikely. However, indirect transmission can occur if an infected person contaminates the environment and oocysts have sufficient time, under appropriate conditions, to become infectious. For example, *Cyclospora* may be transmitted by ingestion of water or food contaminated with oocysts. In 1996, a large outbreak of *Cyclospora* infection in the United States and Canada was associated with consumption of imported raspberries [1]. How common the various modes of transmission and sources of infection are is not yet known, nor is it known whether animals can be infected and serve as sources of infection for humans.

Who is at risk for infection?

Persons of all ages are at risk for infection. Persons living or traveling in developing countries may be at increased risk, but infection can be acquired worldwide. In the United States, most cases of *Cyclospora* infection are detected April through August.

What are the symptoms of infection?

The incubation period between acquisition of infection and onset of symptoms averages 1 week. *Cyclospora* infects the small intestine and typically causes watery diarrhea, with frequent, sometimes explosive, stools. Other symptoms can include loss of appetite, substantial loss of weight, bloating, increased flatus, stomach cramps, nausea, vomiting, muscle aches, low-grade fever, and fatigue. If untreated, illness may last for a few days to a month or longer, and may follow a remitting-relapsing course. Some infected persons are asymptomatic.

How is infection diagnosed?

Identification of this parasite in stool requires special laboratory tests that are not routinely done (see section on laboratory diagnosis). A single negative stool specimen does not rule out the diagnosis; three or more specimens may be required. Stool specimens should also be checked for other microbes that can cause a similar illness.

How is infection treated?

Trimethoprim/sulfamethoxazole (TMP/SMX), or Bactrim*, Septra*, or Cotrim*, has been shown in a placebo-controlled trial to be effective treatment for *Cyclospora* infection [2]. Adults should receive TMP 160 mg plus SMX 800 mg (one double-strength tablet) orally twice a day for 7 days. Children should receive TMP 5 mg/kg plus SMX 25 mg/kg twice a day for 7 days. Patients with AIDS may need higher doses and long-term maintenance treatment [3].

No alternative antibiotic regimen has been identified yet for patients who do not respond to or are intolerant of TMP/SMX. Anecdotal or unpublished data suggest that the following drugs are ineffective: trimethoprim, azithromycin, nalidixic acid, the quinolones, tinidazole, metronidazole, quinacrine, tetracycline, doxycycline, and diloxanide furoate. Approaches to consider for treatment of such patients include observation and symptomatic treatment, use of an antibiotic whose effectiveness against

Cyclospora is unknown or is based on limited data (e.g., albendazole, paromomycin, pyrimethamine), or desensitization to TMP/SMX. The latter approach should be considered only for selected patients who require treatment, have been evaluated by an allergist, and do not have a life-threatening allergy.

How is infection prevented?

Based on currently available information, avoiding food or water that may be contaminated with stool is the best way to prevent infection. Reinfection can occur.

Key points for the laboratory diagnosis of *Cyclospora* [4]:

1. To maximize recovery of *Cyclospora* oocysts, first concentrate the stool specimen by the Formalin-ethyl acetate technique (centrifuge for 10 minutes at 500 x g) and then examine a wet mount and/or a stained slide of the sediment.

2. *Cyclospora* oocysts are 8-10 microns in diameter (in contrast, *Cryptosporidium parvum* oocysts are 4-6 microns in diameter).

3. Ultraviolet epifluorescence microscopy is a sensitive technique for rapidly examining stool sediments for *Cyclospora* oocysts, which autofluoresce (*Cryptosporidium parvum* oocysts do not). If suspect oocysts are found, bright-field microscopy can then be used to confirm that the structures have the characteristic morphologic features of *Cyclospora* oocysts (i.e., are nonrefractile spheres that contain undifferentiated cytoplasm or refractile globules).

4. On a modified acid fast-stained slide of stool (the technique used by most laboratorians), *Cyclospora* oocysts are variably acid fast (i.e., may be unstained or stain from light pink to deep red). Unstained oocysts may have a wrinkled appearance; it is important to distinguish oocysts from artifacts that may be acid fast but do not have the all-important wrinkled morphology of the oocyst wall.

5. Using a modified safranin technique (recently published), oocysts uniformly stain a brilliant reddish orange if fecal smears are heated in a microwave oven during staining [5]. If epifluorescence microscopy is available, the stained slide can first be examined with this technique and suspect oocysts reexamined with bright-field microscopy.

6. Although not recommended as an optimal technique for detection of *Cyclospora*, on a trichrome-stained slide of stool, the oocysts appear as clear, round, and somewhat wrinkled spheres, either 8-10 microns in diameter or slightly smaller because of shrinkage during the staining process.

References:

1. CDC. Update: Outbreaks of *Cyclospora cayetanensis* infection - United States and Canada, 1996. MMWR 1996;45:611-2.

2. Hoge CW, et al. Placebo-controlled trial of co-trimoxazole for cyclospora infections among travellers and foreign residents in Nepal. Lancet 1995;345:691-3.

3. Pape JW, et al. *Cyclospora* infection in adults infected with HIV: clinical manifestations, treatment, and prophylaxis. Ann Intern Med 1994;121(9):654-7.

4. Garcia LS, et al. Diagnostic medical parasitology. 3rd ed. Washington, DC: American Society for Microbiology, 1997:66-9.

5. Visvesvara GS, et al. Uniform staining of *Cyclospora* oocysts in fecal smears by a modified safranin technique with microwave heating. J Clin Microbiol 1997;35:730-3.

For more information:

Hoge CW, et al. Epidemiology of diarrhoeal illness associated with coccidian-like organism among travellers and foreign residents in Nepal. Lancet 1993;341:1175-9.

Huang P, et al. The first reported outbreak of diarrheal illness associated with *Cyclospora* in the United States. Ann Intern Med 1995;123:409-14.

Ortega YR, et al. Cyclospora species - a new protozoan pathogen of humans. N Engl J Med 1993;328:1308-12.

Soave R. *Cyclospora*: an overview. Clin Infect Dis 1996;23:429-37.

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National Center for Infectious Diseases
Centers for Disease Control and Prevention
Atlanta, GA

Updated: 04/18/97 11:10:37
URL: **http://www.cdc.gov/ncidod/diseases/cyclo/cyclohp.htm**

ATTACHMENT C

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Centers for Disease Control
and Prevention (CDC)

Memorandum

Date December 20, 1996

From EIS Fellow, Foodborne and Diarrheal Diseases Branch, DBMD, NCID

Subject Foreign Trip Report - Guatemala

To Assistant Director for International Health, CDC
Through Director, DBMD
Chief, FDDB

I DATES AND PLACES OF TRAVEL

July 9, 1996 to August 8, 1996

Asociacion Gremial de Exportadores de Productos Non Tradicionales, Guatemala City

Warehouses and raspberry farms in the departments of Chimaltenango, Sacatepequez, Guatemala, and Santa Rosa

II PURPOSE OF TRAVEL

To investigate the source of contamination of raspberries associated with a multi-state outbreak of *Cyclospora cayetanensis* infections.

III PRINCIPAL ASSOCIATES AND PERSONS CONTACTED

Direccion General de Servicios de Salud
Carlos Flores, MD

Asociacion Gremial de Exportadores de Productos No Tradicionales, GEXPRONT
Members of the Commission of Berries

Medical Entymology Research and Training Unit
Robert Klein, PhD, Director
Eduardo Ibanez, MS

United States Embassy
Richard Drennan, U.S. Agricultural Affairs Officer

IV ACTIVITIES AND ACCOMPLISHMENTS

See attached final report

- reflects information as of the date only - [illegible]
- (NOTE: exporter initials (eg, exporter #) do not all match those in the New England Journal paper

DATE: December 20, 1996

FROM: Marta Ackers, M.D.
Foodborne and Diarrheal Diseases Branch, DBMD, NCID
Centers for Disease Control and Prevention

SUBJECT: **Final Report, Investigation to Identify the Source of Contamination of Guatemalan Raspberries Associated with Cases of *Cyclospora cayetanensis* Infection, Guatemala, July -August 1996**

TO: **Rodolfo Quezada**
President, Commission of Berries,
Guatemalan Association of Exporters of Non-Traditional Products

Background

From May 3, 1996 to June 14, 1996 there were 54 events (e.g. luncheons, receptions, and parties) in the United States and Canada that were associated with cases of infection with the parasite, *Cyclospora cayetanensis* (Figure 1). All but one of these events occurred in states or provinces east of the Rocky Mountains. Epidemiologic investigations of the clusters have demonstrated an association between *Cyclospora* infection and consumption of fruit dishes containing raspberries alone or mixed with other berries and fruit. Traceback investigations done at the local, state, and federal levels have indicated that the raspberries associated with these clusters originated in Guatemala.

On July 9, 1996, Marta Ackers, M.D., EIS fellow, Foodborne and Diarrheal Diseases Branch, NCID, CDC, joined Luis Solorzano, M.S., investigator, San Francisco Branch, Food and Drug Administration (FDA) in Guatemala to initiate traceback investigations to identify a unifying hypothesis, e.g., a single farm, warehouse, transportation hub, or common handling practice which might be the source of contamination for the berries. On July 10, 1996 they were joined by Kimberley Donaldson, M.S., microbiologist, DPD, NCID for further assistance. Victor Caceres, M.D., M.P.H., EIS fellow, Division of Field Epidemiology, EPO, CDC, and Jonathan Winickoff, medical student, Foodborne and Diarrheal Diseases Branch, joined the investigation on July 24, 1996

Guatemalan Raspberry Exports

Berries (raspberries and blackberries) are not native to Guatemala. They were first introduced in Guatemala for export in the late 1980's. Berries are grown by individual farmers and then either exported directly to foreign markets or sold to Guatemalan companies for export. Blackberries are grown and exported by more producers due to their less stringent growing requirements.

Raspberries have been more difficult to cultivate due to the inability of some strains to adapt to the Guatemalan climate. There is also a greater degree of capital investment required to both grow them and bring them to market. However, because raspberries yield better market prices, they have been recently gaining export volume.

5 lb if just count the fruit

Guatemalan fresh raspberry exports (hereafter referred to as raspberry exports) have grown tremendously in the last few years. Both the number of producers and land under cultivation have increased. Total raspberry exports increased from 184,606 flats in the 1994-95 harvest year (October to September) to 299,317 flats in the 1995-96 harvest year (Figure 2). One flat of raspberries weighs approximately 5 kg. In May 1995, 7 Guatemalan exporters reported exporting approximately 55,951 flats of raspberries to the United States; in May 1996, 8 Guatemalan exporters exported a total of 75,824 flats (Figure 3).

Although Guatemala exports raspberries to Europe, the United States receives 98% of Guatemalan raspberry exports. Our proximity to Central America permits Guatemalan raspberries to enter the United States and reach their final destination within hours to several days. This quick transit time suits the raspberries' storage requirements as they have a shelf-life of only 7-10 days once harvested. Miami is the largest port of entry for U.S. raspberry exports (88%) followed by minimal direct exports to New York, Houston, Washington, D.C., and Los Angeles. Raspberry exports from Guatemala occur year-round, but larger quantities are exported in October, November, May, and June. These quantities coincide with peak harvest seasons, and the low seasons for Chilean and California raspberries

Raspberry Production and Exportation

Description

Raspberry production centers are located in the Departments of Chimaltenango, Sacatepequez, and Guatemala with minimal production in Santa Rosa, Jalapa, and San Marcos (Figure 4). Raspberries thrive at altitudes of 1,000 to 1,850 meters above sea level. Lower altitudes are too hot for quality fruit and higher altitudes could expose the berries to damaging frosts.

Raspberries are grown in a variety of locations and quantities. Farms are measured in terms of manzanas (1 manzana = 7,000 square meters). Farms generally range in size from 4 to 30 manzanas. During harvest, growers obtain approximately 1,200 flats of raspberries per manzana. With two harvests annually, a grower may expect 2,400-3,000 flats of berries per manzana.

Most raspberry farms are businesses, and their owners do not directly live on the premises. Their fields are managed by employees who may or may not live on the farm. Occasionally, growers plant other crops in addition to berries, but most farms solely produce berries.

Irrigation

Raspberries thrive in the porous volcanic or sandy soil found in the 60 km radius surrounding Guatemala City. Raspberries are grown on terraced or flat land in rows with wooden posts and wires or strings spread between the posts to support the plants. The raspberry bushes are approximately 4-5 feet in height, with the raspberries located at least 3 feet from the base of the plant. Raspberries require extensive irrigation during the dry season and harvest. Because direct application of water damages the quality of the fruit, water is delivered to the base of the plants by drip irrigation systems. A drip irrigation system generally consists of a mechanical well (100-500 ft in depth depending on the region) which pumps water through a sand filter, followed by 2 to 4 mesh filters. This water then passes through a series of 2-inch and 1-inch in diameter irrigation pipes until they eventually lead to black plastic irrigation piping which can be seen above ground. Some farms pump the water into large reservoirs and from these reservoirs the water passes to the large irrigation pipes. Valves placed between the larger and smaller irrigation pipes are then closed and opened daily depending on which portions of the fields are to be irrigated. The black plastic irrigation piping which is 16 mm in diameter, is laid directly on the soil at the base of the plants. At 30 cm intervals there are small holes in the piping which permit drops of water to be applied directly to the soil beneath the plants.

Agents applied to berries

Most farms administer fertilizers via injection through their drip irrigation systems. In addition, most farms use chicken fertilizer for seedlings, and some farms also apply it to grown raspberry plants before harvest. Three other groups of agents, fungicides, insecticides, and growth regulators, are applied directly to the berries before harvest.

The fungicides applied directly to the plant and berries include the following: Captan, Dicloran, Benomil, Vinclozolin, Iprodiona, and Triadimefon. Fungicides are applied to ward off botrytis or gray mold, the most common and one of the most serious diseases of raspberries. Raspberries are especially at risk for fungus infections from the persistent rains during the May-June harvest. When large amounts of rain are expected the frequency of fungicide application is increased. Some fungicides are applied the day of picking and others, several days before harvest, to insure levels are safe for human consumption. For example, Iprodonia is applied the day of harvest, Triadimefon is applied the day before. The insecticides sprayed on raspberries include: Malation, Diazinon, Dicofol, Carbaryl, Endosulfan, Naled, and Fenamifos. These agents are sprayed between 1-20 days before harvest. Growth regulators are the third group of agents applied to the berries. Most of the growth regulators are sprayed on young plants before they bear fruit. One growth regulator, a mixture of nitrogen, phosphorous and potassium, is sprayed every 15 days during the harvest season.

Pesticides (fungicides and insecticides) are applied to raspberry plants after mixing with water by either spraying the mixture onto the soil or directly onto the plant throughout both the growing and harvest seasons. The water that is used for mixing includes water from wells, reservoirs, or water from rivers or springs in a few cases. Pesticides are generally mixed with water in large 50-gallon plastic containers before application. These 50-gallon containers are generally cleaned once a week. From these containers the pesticide is poured into backpacks which are carried by workers who spray the pesticide directly onto the plant or on the soil below. Larger farms use a "parigüela" or motorized pump machine with two hoses. One hose retrieves pesticide from the 50-gallon container and the other is used for application of the pesticide. During the application process, one worker will spray the plants while another worker carries and straightens the hose.

Harvest/Storage

Once seedlings are planted it takes approximately 6 months until flowering and then another 40-50 days to produce raspberries ready for harvest. Depending on their size, farms employ anywhere from 10-80 pickers and classifiers, predominantly women. Individual pickers working from approximately 7 am to 3 pm can provide 4-6 flats daily. Most farms require harvesters to place raspberries in individual plastic baskets within a larger plastic or wooden basket. Ripe berries are picked with bare hands and placed into the individual plastic baskets with a preliminary sorting done for fresh versus frozen export. Once the individual baskets are filled, the larger basket and its contents are taken to a classification shed where the raspberries are sorted again by another worker. This worker sorts the berries for export into half-pint translucent plastic containers or clamshells. Each clamshell has slits on the side and holes on the top and an absorbent blotter on the bottom which soaks up any berry juice. Once filled, the clamshell is placed in a cardboard flat with eleven other clamshells. The clamshells may be opened for visual inspection by the exporters, but are not handled again until they reach the United States.

After harvest and placement in the clamshells, the berries are cooled in refrigerated rooms at individual farms or transported by car or truck to cold rooms at neighboring farms or by refrigerated trucks, vans, or cars to exporters' warehouses. Transportation of berries is by refrigerated or non-refrigerated vehicles depending on the distance and volume of berries involved. Ultimately all berries travel to exporter warehouses for shipping. Immediately upon arriving at exporters' warehouses berries are placed in cold rooms with fans which draw cold dry air to quickly chill the berries to 1°C (34°F) in 40-60 minutes while maintaining a humidity of 90-95%. After being quick-chilled berries are moved to a second cold room for maintenance of temperature and to await further packing.

Shipping

At approximately 10 pm raspberry flats are packed into either E-containers (cardboard boxes approximately 3x3x4 feet in dimension lined with a 1-inch thick insulating layer of Styrofoam and secured by plastic strapping) or pallets (180 flats held together by a nylon fish net and covered top and bottom with a Thermaguard casing) in the cold storage rooms at the warehouses. Individual flats are not wrapped in plastic. A variety of gelpacks depending on the exporter's preference are either placed on the sides of the flats in the E-containers or on top of the pallets to keep the berries cold during international shipping. Exporters A, C, D and E make their own gelpacks at their individual warehouses. Exporter B obtains its gelpacks from the United States. There is no treatment given with carbon dioxide or other chemicals to extend the shelf-life of the berries.

Filled E-containers and pallets are transported in refrigerated trucks from exporter warehouses to the Guatemala City Airport. These trucks arrive at the airport between 11 pm - 12 am. Upon arrival at the airport, berries to be transported on cargo planes or national carriers enter Combex, the cargo loading and storage area, where they are placed in cold rooms until loading of cargo planes occurs between 2-4 am. Berries to be exported on US carriers or other passenger planes are taken later to the cargo loading area of those individual airlines. There is no opening of the E-containers or pallets at the airport.

Inspection

As stated above, 98% of Guatemalan raspberry exports are sold in the United States. Miami, Florida is the principal port of entry for 88% of these raspberries. Raspberries are transported from Guatemala to Miami in both passenger and cargo planes. After arriving in Miami, berries are unloaded from the planes and pass through one of 4 United States Department of Agriculture (USDA) cargo clearance areas. American Airlines, Challenge Air Cargo, Aviateca, or Gelco, a major importer based at the airport, each have their own cargo clearance area. Because Gelco is based at the Miami airport it is the only importer which clears its own raspberry shipments at its warehouse. The other importers clear their shipments through the airlines' cargo clearance areas. At each cargo area, approximately 2% of each exporter's shipment is opened, and the berries are inspected by USDA for insects.

Each cargo inspection area contains one table where all produce and flowers are inspected. At the cargo clearance area E-containers and pallets are opened, and the gel packs are discarded. USDA inspectors remove clamshells from the flats, open them, and dump their contents on the table. The berries are touched with bare hands on a bare table. Occasionally, a piece of white blotting paper is placed under the berries to enhance contrast and help with searching for insects. After inspection the berries are placed back in their clamshells, replaced in their flats, and returned to their storage locations before being collected by the Miami-based importers.

After inspection, some Miami-based importers bring the raspberry flats to a blast cooler for rapid cooling. After 1-1 ½ hours of cooling at 34°F, the berries are moved to large refrigerated storage rooms (maintained at 34-38°F) where they remain until they are shipped to other distributors. Raspberries flats are shipped to other distributors in two ways. If they are transported in a non-refrigerated truck they are repackaged into E-containers with several new Polar® gelpacks placed between the flats of the top layer. If they are shipped in a refrigerated truck, the flats are stacked on a pallet without gelpacks

Chilean raspberries undergo pre-inspection by USDA in Chile and do not pass through the cargo clearance areas. Chilean raspberries otherwise undergo the same process of unpacking, cooling, and storage as the Guatemalan berries.

Tracebacks

From May 3 - June 14, 1996, 54 events were associated with cases of *Cyclospora* infection reported from 14 U.S. states, the District of Columbia, and 2 Canadian provinces. No one caterer, distributor, or shipper was common to all these clusters. Epidemiologic investigations of the clusters have demonstrated an association between *Cyclospora* infection and consumption of fruit dishes containing raspberries alone or mixed with other berries or fruits. Traceback investigations indicated that the raspberries associated with these clusters of *Cyclospora* infections originated in Guatemala.

For 29 (54%) of the 54 clusters of *Cyclospora* infections there was documentation to establish complete tracebacks. These high confidence level tracebacks were accomplished by interviews with local distributors and review of invoices and airway bills of the raspberry shipments supplying the 29 corresponding events. These tracebacks led to 11 importers who received shipments of Guatemalan raspberries from 5 exporters (Exporters A, B, C, D, and E) from May 1- June 5, 1996. For 21 (72%) of 29 clusters, Guatemala was the sole possible source of the raspberries served at the event. For the remaining 8 (28%) Guatemala was a probable source for the raspberries, (i.e., Guatemala was one of two or more possible sources).

Tracebacks for 25 (46%) of the 54 clusters were not included in the analysis. Four (7%) of the 54 clusters involved inadequate data about exposures at the events and had very complicated tracebacks implicating Guatemala as a probable source for the raspberries. These tracebacks led to multiple shipments from Exporters B, E, F, and I. For 2 (4%) of the 54 clusters, some evidence suggested that a shipment of raspberries from Guatemala probably was used; however, copies of the invoices were not available to trace to the exact shipment(s). For the remaining 19 (35%) of the 54 clusters, the retailer or distributor from which the raspberries were bought could not be identified.

High confidence level tracebacks for 29 clusters led to 47 raspberry shipments. Of these 47 shipments to the United States which could have been the source of the raspberries that were served at the events, 41 (87%) entered the United States through Miami, 3 (6%) entered through Washington, D.C., 2 (4%) entered Houston, and 1 (2%) came in through Los Angeles. Miami could have been the sole port of entry for all but one raspberry shipment associated with the events, (i.e., with exception of one event, at least one shipment per event entered through Miami). The implicated shipments traveled on five airline carriers: Challenge Air Cargo, Aviateca (cargo and passenger planes), TACA, Continental, and American Airlines. Time interval from shipment to consumption ranged from 3 to 21 days, median 7 days. Eighteen (62%) of 29 tracebacks had more than 1 possible shipment identified per cluster or event and more than 1 possible farm identified per shipment (shipments ranged from 40-1,087 flats, and included raspberries from 1 to 28 different farms). Figure 5 shows the dates associated with implicated shipments from Exporters A-E and these exporters' total daily shipments of raspberries to the United States from May 1 to June 30, 1996.

For 25 of the 29 high-confidence tracebacks, a single exporter was identified. Exporter A was the sole supplier of raspberries in 18 (62%), Exporter B for 5 (17%), Exporter D for one (3%), and Exporter E for one (3%). The remaining 4 clusters were traced to shipments from more than 1 exporter involving Exporters A, B, C, and D.

Exporter A was the sole supplier for 18 clusters of *Cyclospora* infections and could have been a supplier for another 2 clusters (i.e., it supplied one of at least 2 shipments from different exporters linked to a cluster). An analysis of the 18 clusters of *Cyclospora* infections to which Exporter A was the sole supplier revealed that each of 4 of 36 farms shipping from May 1 - June 5 could have been linked to 16 of 18 clusters (Table 1). That is, any one of these four farms could have accounted for 16 clusters linked to raspberries from Exporter A (not necessarily the same 16 clusters for all 4 farms). Two other farms could have been linked to 15 of 18 clusters and 1 other farm to 14 of 18 clusters.

Of the 7 farms that each could account for at least 14 of the 18 clusters, 6 farms were located in the same region and began harvesting at the same time. Due to their proximity to Guatemala City, these 6 farms were almost always on the same shipments out of Guatemala City between May 1 - June 5 (Figure 6). There were very few shipments in which raspberries from only one of these farms were present. None of these farms sold raspberries to any other exporter during the outbreak period. Six of these 7 farms obtained their water from wells; one of these farms also distributed its water through a tank. The seventh farm (A170) obtained its water from a river.

Twelve farms, including the seven linked to 14 or more of the clusters attributed to Exporter A, were visited by CDC and FDA investigators. Samples of agricultural water (obtained by filtering 10-100 gallons of water from the well, reservoir, or river), soil, raspberries and raspberry plant material were collected from these farms (Table 2)

An analysis of the 5 clusters of *Cyclospora* infections to which Exporter B was the sole supplier revealed that 1 of 17 farms shipping from May 1 - June 5, 1996 could account for all 5 of the clusters attributed to Exporter B, 2 other farms could each account for 4 of 5 clusters attributed to Exporter B, and a fourth farm could account for 3 of 5 clusters (Table 3). Only one of these farms (B148) sold raspberries to another exporter (Exporter E) during May 1 - June 5, but was not associated with implicated shipments from Exporter E. Four farms were visited and samples of water, raspberry plant material, and soil were obtained (Table 2). Of the 4 farms linked to 3 or more of the 5 clusters, 3 obtained their water from wells which then passed through reservoirs, the fourth (B2) obtained its water from a spring.

Exporter C was possibly associated with 3 clusters, but was not the sole possible supplier for any of them. Exporter C only exported raspberries from its farm. It did not receive raspberries from other farms. This farm was visited and samples of well water, soil, and latrine contents were obtained (Table 2).

Exporter D was the sole supplier for 1 cluster. Raspberries from 4 farms contributed to the shipment linked to the cluster in which Exporter D was the sole supplier. These raspberries came from the Exporter D's two farms and from two other farms. One of these other farms also supplied raspberries to Exporter A, but was not associated with implicated shipments from Exporter A. The other farm also supplied raspberries to Exporter A and B, but was not associated with implicated shipments from Exporter A or B. One of the farms owned by Exporter D was visited.

Exporter E was the sole supplier for 1 cluster. Exporter E shipped raspberries from 9 farms during the May-June harvest. The raspberries for the one shipment linked to the cluster were from 3 farms. One of those farms was visited and samples of water, berries, and soil were obtained (Table 2).

The samples of water, soil, raspberry plants, and latrine contents that were obtained were sent to CDC for *Cyclospora* testing. Ten additional water samples obtained on August 7 and 8 at the 7 farms linked to 14 or more of the 18 clusters associated with Exporter A and 3 farms linked to the 5 clusters associated with Exporter B were tested for fecal coliforms at the Instituto Nutricional de Centroamerica y Panama (INCAP).

Environmental Results

Fifteen water samples were tested for *Cyclospora* oocyts and were negative. Three samples of latrine contests were tested for *Cyclospora* oocyts and were negative. Results of 18 soil samples, 3 raspberry samples, and 14 samples of raspberry plant material are pending.

Five of 10 samples of agricultural water tested for fecal coliforms at the 10 farms supplying Exporters A and B demonstrated elevated levels of fecal coliforms (>15 most probable number [MPN] per 100 ml) (Table 4). One of these farms (A170) obtained its water from a river. The other four farms obtained their water from wells, of which 2 (B4 and B1) pumped this water into reservoirs.

Hypotheses for *Cyclospora* Contamination

Contamination of raspberries lasted for 6 weeks and did not appear to be associated exclusively with any one farm, raspberry shipment, exporter, importer, distributor, or foodhandler. The wide range of event locations, shippers, and distributors made the possibility of raspberry contamination occurring in the United States highly unlikely. Exporter A was the sole supplier of 18 of 25 clusters of *Cyclospora* infection with high confidence level tracebacks to single exporters. Exporter B was the sole supplier for 5 of these 25 clusters. Based on Exporter A's percentage of exports to the United States in May 1996, this is higher than would be expected (Table 5). This suggests that the contamination was not uniformly distributed across all exporters

Based on the extensive epidemiologic and traceback investigations, we conclude that a relatively small number of farms would have accounted for the 25 clusters of *Cyclospora* infections with high confidence level tracebacks attributed to sole suppliers; we refer to those farms as the high risk farms. These farms include the 7 farms accounting for 14 or more of 18 clusters associated with Exporter A, and the 3 farms accounting for 4 or 5 of 5 clusters linked to Exporter B. Other farms may be linked to Exporters D and E, but there are not sufficient data available to implicate farms supplying these exporters.

Among this group of high-risk farms, a smaller number could actually account for most the clusters, although we were unable to identify which specific farm that would be. For examples any one of the 4 farms supplying Exporter A could have accounted for 16 of the 18 clusters traced to that exporter alone, and one farm could have accounted for all 5 of the clusters related to Exporter B. Thus, 2 farms could possibly have accounted for 21 of the 25 clusters traced to a single source, and as few as 5 could have accounted for all 25 (Table 6).

Various hypotheses are being considered for how raspberries became contaminated with *Cyclospora*. Two hypotheses relating to water sources and human contact are discussed in detail below. In addition, the possibilities of soil or animals serving as sources of contamination are being considered. It is not yet known if animals are infected with *Cyclospora cayetanensis* and whether they can serve as sources of infection for humans.

In previous outbreak investigations water has been reported as a transmission vehicle for *Cyclospora*. Therefore, water must be seriously considered as a possible source for the contamination of the raspberries. Eight of the 10 implicated raspberry farms from Exporters A and B obtain their water from mechanical wells, but two obtain their water from a river and underground spring. Additionally, although 8 of these farms have mechanical wells, 3 farms pump the water from wells into reservoirs or tanks to aid with water pressure or shortages in water supply. These reservoirs may be open, closed, or covered with netting to prevent debris from entering the water. All water regardless of its source usually passes through one to four filters before being used for irrigation. The smallest filters are 120 microns which are inadequate to filter out *Cyclospora* oocyts which are 8-10 microns in diameter. *Cyclospora* contamination of the water supplies could occur from human, animal, or surface water contamination. In at least one farm, the river from which the farm obtained its water supply was noted to have people bathing in it upstream in addition to garbage floating in it. Reservoirs and shallow wells are at increased risk for surface water contamination during the rainy season. Once contaminated this water could reach the berries through pesticide application.

There are limitations of water testing to detect the presence of *Cyclospora*. Although, the water samples we collected and examined for *Cyclospora* oocyts were negative these samples were collected in July 1996, almost 2 months after the majority of the *Cyclospora* clusters had occurred. Implicated farms were no longer in production at the time of water collection, and water was not being used for irrigation or pesticide application. In addition, the techniques used to test for the presence of *Cyclospora* are relatively insensitive.

In September 1996, Dr. Frank Bryan conducted further studies and investigation into farms' water sources, and his forthcoming report will address these and other environmental issues in more detail.

Human contact with raspberries occurs during picking, classifying, and inspecting. With the onset of the rainy season, the Guatemalan population experiences the "Mal de Mayo" or increases in diarrheal illnesses. These illnesses reportedly affect all social strata. Although *Cyclospora* has been detected in stool samples in Guatemala its prevalence in the general population is not known. It is possible that some diarrheal illnesses experienced at this time could be due to *Cyclospora* infections. It is therefore possible that workers at the farms, including pickers and classifiers, could excrete *Cyclospora* and contaminate fruit if infected at this time. Pickers may touch berries that are not picked until days later. However, *Cyclospora* is not infectious when first excreted so one would also need to postulate sporulation on the berries. The time required for this process is unknown. In addition, to account for the outbreaks reported, widespread contamination of berries by many workers would be necessary, and this seems unlikely.

In conclusion, it seems most likely that contamination of berries occurred from the environment, most likely from water. Further work is needed to determine the reservoirs for *Cyclospora*, its survival in the environment, and its life cycle.

Conclusions:

We conclude that:

1) Guatemalan raspberries caused a multi-state outbreak of cases of *Cyclospora* infection.

2) No common exporter, warehouse, or packaging method was identified.

3) Not all farms were equally likely to be implicated. As few as two farms could account for 21 (84%) of 25 clusters of *Cyclospora* infection traced to a single source, and as few as five farms could account for all 25.

4) The most likely mode of transmission was water sprayed on berries in pesticide solutions. Other modes of transmission cannot be excluded

Recommendations

1. Water directly applied to berries should meet the standards for potable water as defined by the World Health Organization guidelines (Tables 7 and 8). This includes water used to mix pesticides and that used for drinking and handwashing by workers.

2. Handwashing facilities and toilet paper should be available near all latrines and toilets for farm workers. Potable running water rather than communal washing basins should be used.

3. Plastic baskets and clamshells should be clean and dry before being used. Berries should not be classified or examined directly on table surfaces. Blotting paper should be used and changed frequently to avoid the risk of cross contamination.

4. Foods and items containing soil and particulate matter, such as flowers, should not be inspected by USDA simultaneously on the same table.

5. Exporters should consider using an adhesive sticker or bar code on each flat to identify the individual farms. The sticker could be scanned or peeled off by the last retail stablishment receiving the berries to allow for immediate identification of the farm of origin.

6. Laboratories should develop better isolation techniques and a subtyping method for *Cyclospora* to aid in linking the epidemiologic and distribution data.

7. CDC and the Guatemalan Association of Exporters of Non-Traditional Products should continue their collaborative working relationship to develop a program of surveillance for *Cyclospora* and to continue investigations of potential sources and modes of contamination.

Marta Ackers, M.D.
EIS Fellow
Foodborne and Diarrheal Diseases Branch
Division of Bacterial and Mycotic Diseases
National Center for Infectious Diseases

Table 1

Raspberry farms supplying Exporter A and their links to 18 clusters

Farm	Clusters	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
A163	16/18	x	x	x	x	x	x	x		x	x	x	x	x	x		x	x	x
A4	16/18		x	x	x	x		x	x	x	x	x	x	x	x	x	x	x	x
A178	16/18	x	x	x	x	x		x	x	x	x	x	x	x	x		x	x	x
A49	16/18	x	x	x	x	x	x	x		x	x	x	x	x	x		x	x	x
A170	15/18		x	x	x	x	x	x	x	x	x	x		x		x	x	x	x
A23	15/18		x	x	x	x		x	x	x		x	x	x	x	x	x	x	x
A24	14/18	x	x	x	x	x		x	x	x	x	x		x			x	x	x
A87	13/18	x	x	x	x	x	x	x		x			x		x		x	x	x
A103	13/18		x	x	x	x		x		x	x		x		x	x	x	x	x
A21	12/18	x	x	x	x	x				x	x	x		x		x	x		x
A111	11/18		x	x	x	x			x		x	x		x		x	x		x
A22	10/18		x	x	x	x				x			x		x		x	x	x
A33	10/18		x	x	x	x			x	x	x					x	x		x
A61	10/18		x	x	x	x			x	x	x					x	x		x
A3	9/18		x	x		x		x				x	x	x	x		x		
A161	9/18		x	x	x	x			x		x			x			x		x
A196	8/18				x	x		x			x		x		x	x		x	
A2	7/18		x			x				x				x		x	x		x
A39	7/18	x	x	x		x										x	x	x	
A85	7/18		x	x	x	x				x						x			x
A43	6/18				x	x		x		x								x	x
A153	6/18		x	x	x			x										x	x
A40	6/18	x	x	x									x		x		x		
A150	5/18		x	x		x		x									x		
A84	4/18				x	x		x										x	
A132	3/18				x	x				x									
A108	2/18				x	x													
A128	2/18	x	x																
A162	2/18				x	x													
A38	1/18					x													
A176	1/18					x													
A53	1/18					x													
A302	1/18			x															
A314	1/18					x													

Table 2

Environmental samples collected from raspberry farms supplying Exporters A, B, C, and E

Farm	Water	Soil	Plant material	Raspberries	Latrine contents
A163	1	1	1		
A4	1	1	1		
A178		1	1		
A49		1			
A170	1	1	1		
A23	1	1	1		
A24		1	1		
A87		1			
A103	1	1	1		
A22	1	1	1	1	
A33	1	1	1		
A161	1	1	1	1	
B4	1	1	1		1
B2	2	1	1		1
B148	1	1	1		
B1	1	1			
C1	1	1			1
E1	1	1	1	1	

Table 3

Raspberry farms supplying Exporter B and their links to 5 clusters

Farm	Clusters	1	2	3	4	5
B4	5/5	x	x	x	x	x
B2	4/5		x	x	x	x
B148	4/5		x	x	x	x
B1	3/5	x	x	x		
B11	2/5		x	x		
B12	2/5		x	x		
B15	2/5		x	x		
B5	1/5			x		
B159	1/5			x		

Table 4

Fecal coliform results from raspberry farm water samples

Farm	Fecal coliform count (MPN/100ml)
A163	4
A4	220
A178	<2
A49	17
A170	≥1600
A23	<2
A24	<2
B4	≥1600
B2	<2
B1	17

Table 5

Distibution of 25 high-confidence tracebacks to a single source by exporter

Exporter	Tracebacks (%)	Reported May exports to the United States (%)*
A	18/25 (72)	27
B	5/25 (20)	40
C	0/25 (0)	12
D	1/25 (4)	6
E	1/25 (4)	3
F	0/25 (0)	4
G	0/25 (0)	2
I	0/25 (0)	7
A, B, D, E	25/25 (100)	76

* As reported by each exporter

Table 6

Minimum estimates of number of farms and exporters that could account for 25 clusters with high-confidence tracebacks to a single exporter

No. farms	No. exporters	No. clusters accounted for (%)
1*	1	16/25 (64)
2	2	21/25 (84)
3	2	23/25 (92)
4	3	24/25 (96)
5	4	25/25 (100)

*Which could be any one of four different farms

Table 7

World Health Organization guidelines for bacteriological quality of drinking-water*

Organisms	Guideline value
All water intended for drinking	
E. coli or thermotolerant coliform bacteria	Must not be detectable in any 100 ml sample.
Treated water entering the distribution system	
E. coli or thermotolerant coliform bacteria	Must not be detectable in any 100 ml sample.
Total coliform bacteria	Must not be detectable in any 100 ml sample.
Treated water in the distribution system	
E. coli or thermotolerant coliform bacteria	Must not be detectable in any 100 ml sample.
Total coliform bacteria	Must not be detectable in any 100 ml sample. In the case of large supplies, where sufficient samples are examined, must not be present in 95% of samples taken throughout any 12-month period.

*The absence of coliforms does not guarantee the water is free of *Cyclospora*. This is particularly true if the water is chlorinated because *Cyclospora* (in contrast to coliforms) is highly resistant to chlorine.

Table 8

World Health Organization guidelines of performance objectives for removal of turbidity and thermotolerant coliform bacteria in small-scale water treatment

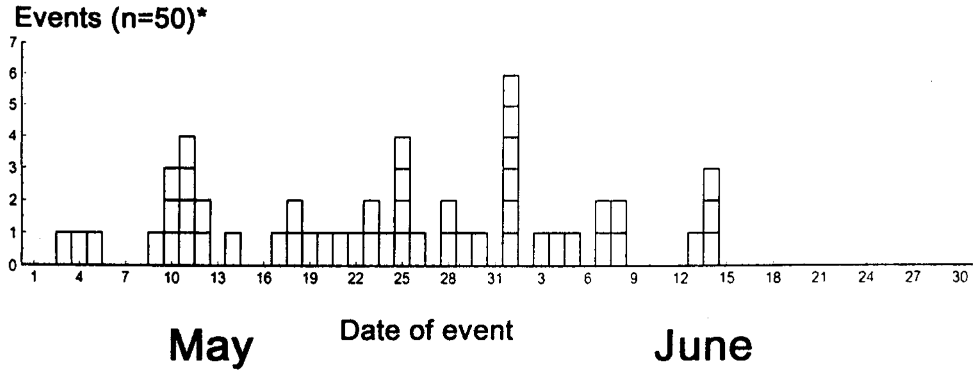
Stage and process bacteria	**Turbidity**			**Thermotolerant coliform**		
	Removal[a] (%)	Average loading (NTU)[b]	Maximum loading (NTU)[b]	Removal[a] (%)	Average loading (per 100ml)	Maximum loading (per 100
Screening	NA[c]	NA	NA	NA	NA	NA
Plain sedimentation	50	60	600	50	1000	10000
Gravel pre-filters (3-stage)	80	30	300	90	500	5000
Slow sand filter	>93	6	60	95	50	500
Disinfection	NA	<1	<5	>99.9	<3	25
Distributed water	NA	<1	<5	NA	<1	<1

[a] Required performance.

[b] NTU, nephelometric turbidity units.

[c] NA, not applicable, Process not designed to remove turbidity and/or bacteria.

Figure 1



Dates of events associated with *Cyclospora* case
North America, May - June 1996

*4 unclear exposures and multiple day events not included

Figure 2

Guatemalan raspberry exports,
by month of export, 1994 - 1996

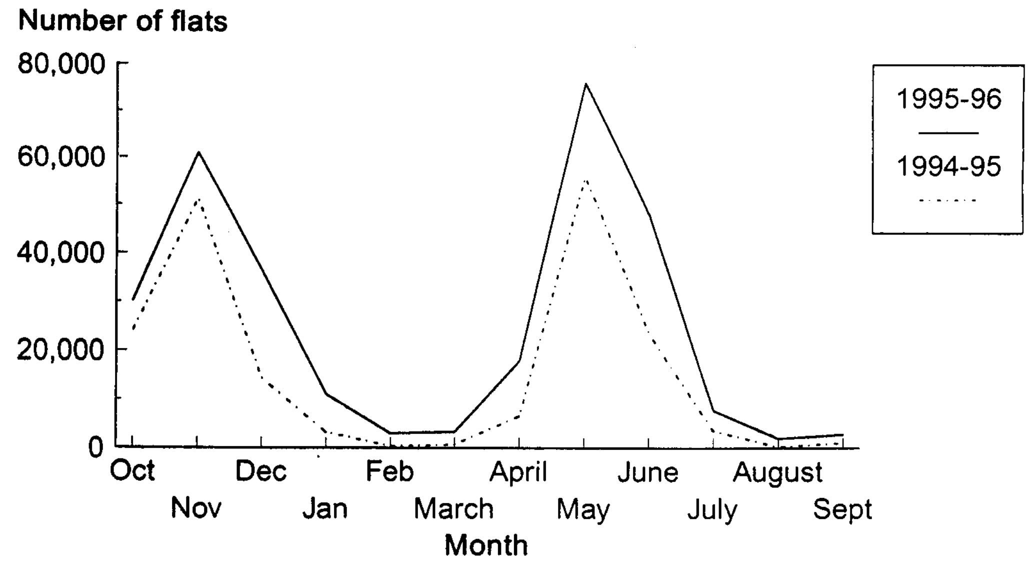
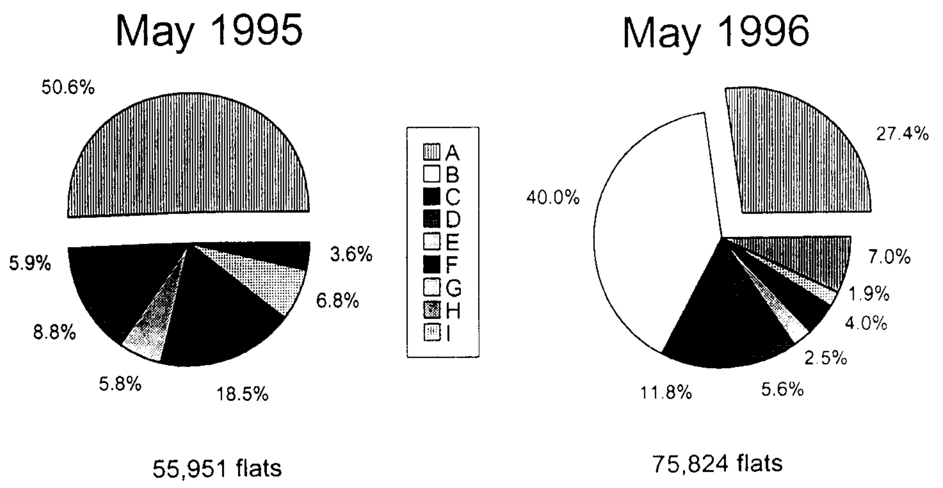


Figure 3

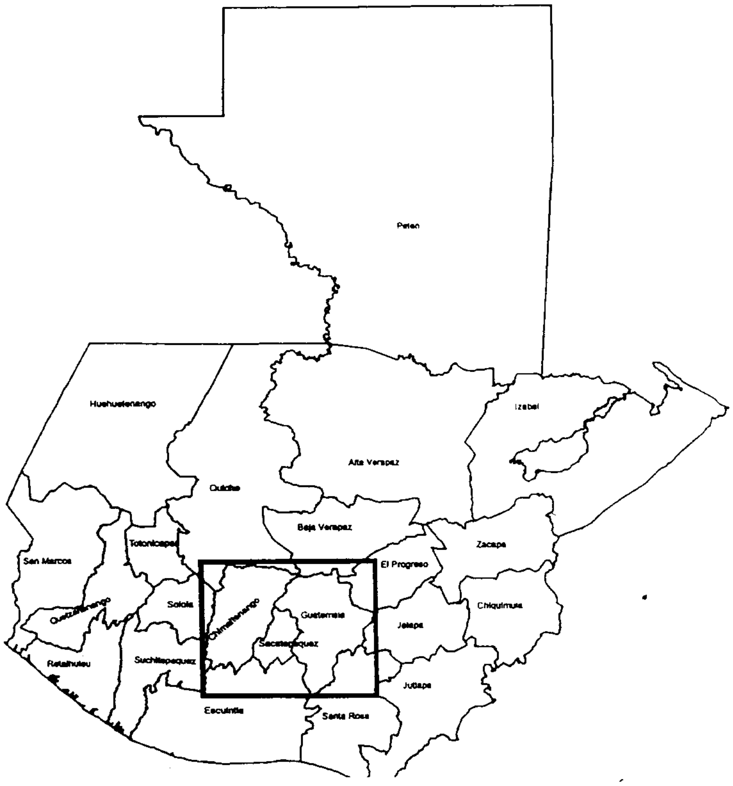
Guatemalan raspberry exports to the United States, May 1995 and 1996, by exporter *



*As reported by individual exporter

Figure 4

Departments of Guatemala



ATTACHMENT D

AN OUTBREAK IN 1996 OF CYCLOSPORIASIS ASSOCIATED WITH IMPORTED RASPBERRIES

BARBARA L. HERWALDT, M.D., M.P.H., MARTA-LOUISE ACKERS, M.D., AND THE CYCLOSPORA WORKING GROUP*

ABSTRACT

Background *Cyclospora cayetanensis* is a parasite that causes gastroenteritis. Until last year most of the documented cases of cyclosporiasis in North America were in overseas travelers. In 1996, a large outbreak of cyclosporiasis occurred in North America. We investigated this outbreak.

Methods Health departments solicited information from clinicians and laboratories on cases of cyclosporiasis, which were then reported to the Centers for Disease Control and Prevention and to Health Canada. We conducted retrospective cohort studies for the cases associated with events (e.g., luncheons) and attempted to identify the sources of the implicated food.

Results A total of 1465 cases of cyclosporiasis were reported by 20 states, the District of Columbia, and 2 provinces. Of these cases, 978 (66.8 percent) were laboratory confirmed and 725 (49.5 percent) were associated with 55 events that were held from May 3 through June 14. Raspberries were definitely served at 50 events and may have been served at 4 events. For 27 of the 41 events for which adequate data were available (65.8 percent), the associations between the consumption of berries (raspberries with or without other berries) and cyclosporiasis were statistically significant ($P<0.05$). For all 29 events for which there were good data, the raspberries definitely came from Guatemala (21 events, 72.4 percent) or may have come from Guatemala (8 events, 27.6 percent). As few as five Guatemalan farms could have accounted for the 25 events for which the raspberries could be traced to a single exporter per event. The mode of contamination of the raspberries remains unclear.

Conclusions This large outbreak of cyclosporiasis in North America in 1996 was associated with the consumption of Guatemalan raspberries. The outbreak illustrates the need to consider that a local cluster of foodborne illness may be part of a widespread outbreak and to pursue investigations of the source of the implicated vehicle. (N Engl J Med 1997;336:1548-56.)

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CYCLOSPORA *cayetanensis*, previously called cyanobacterium like body, was recently established to be a coccidian parasite.[1,2] Cyclospora oocysts do not multiply outside the host. After fecal excretion they do not sporulate and become infectious for days to weeks.[1] The parasite's natural ecology, infective dose, and host range are unknown. It is also not known whether all human isolates belong to the same species (i.e., *C. cayetanensis*), or why in some countries most cases of cyclosporiasis occur from April through August.[1-3]

Cyclosporiasis has a median incubation period of one week, is associated with invasion of enterocytes of the small intestine,[4,5] is manifested by protracted and relapsing gastroenteritis, and is treatable with trimethoprim–sulfamethoxazole.[6] The oocysts of *C. cayetanensis* are 8 to 10 μm in diameter, about twice the size of ***Cryptosporidium parvum*** oocysts, and are identified in stool specimens by the use of modified acid-fast and other stains, the examination of wet mounts under phase-contrast microscopy, and the demonstration of autofluorescence.[1,2,7,8] Sporulation of oocysts (i.e., the development of two internal sporocysts, each with two internal sporozoites) definitively establishes the diagnosis,[1] and techniques based on the polymerase chain reaction[9,10] may also prove useful.

Before 1996, most documented cases of cyclosporiasis in North America were in overseas travelers, and only three small U.S. outbreaks (with a maximum of 45 laboratory-confirmed cases) had been reported.[11-13] In May 1996, several health departments reported cases of cyclosporiasis to the Centers for Disease Control and Prevention (CDC). Ultimately, 978 laboratory-confirmed cases occurring in the spring and summer of 1996 were reported to the CDC and to Health Canada.[14-20]

Although early in the investigation various berries, including strawberries, were considered as possible vehicles of infection, Guatemalan raspberries were ultimately implicated. Raspberries were introduced in Guatemala in 1987 and first exported in 1988. In the past few years, exports have markedly increased, with the United States being the primary market for fresh raspberries; exports peak in May and June (during the rainy season) and October through December (the dry season). The possibility of foodborne transmission of cyclospora has been

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From the Epidemiology Branch, Division of Parasitic Diseases (B.L.H.), and the Foodborne and Diarrheal Diseases Branch, Division of Bacterial and Mycotic Diseases (M.-L.A.), National Center for Infectious Diseases, and the Epidemic Intelligence Service, Epidemiology Program Office (M.-L.A.), Centers for Disease Control and Prevention, Atlanta. Address reprint requests to Dr. Herwaldt at the Centers for Disease Control and Prevention, Division of Parasitic Diseases, 4770 Buford Hwy. NE, Mailstop F22, Atlanta, GA 30341-3724.

*Members of the Cyclospora Working Group are listed in the Appendix.

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considered in previous cases and outbreaks,[21-25] including an outbreak that occurred in Florida in 1995, which may also have been associated with Guatemalan raspberries[12] (and Koumans E: personal communication). Our investigation of the large 1996 outbreak of cyclosporiasis definitively established that cyclospora can be a foodborne pathogen.

METHODS

Epidemiologic Investigation

In the spring of 1996, after an increase in the numbers of cases of cyclosporiasis was recognized, health departments solicited clinicians and laboratories for reports of cases, which were then reported to the CDC and to Health Canada. The CDC encouraged health departments to have reference laboratories (e.g., the CDC) reexamine stool specimens to reconfirm the diagnosis and to submit stool specimens in 2.5 percent potassium dichromate to the CDC for the demonstration of oocyst sporulation.[1]

A cluster of cases of cyclosporiasis was defined as a group of two or more cases among persons who, during May 1 through August 31, 1996, shared at least one meal or food item at an event (e.g., a luncheon or conference) and began to have at least one gastrointestinal symptom 12 hours to 14 days later. At least one case per cluster had to be laboratory confirmed; clinical case definitions for probable cases varied (Table 1). Health departments investigated clusters by conducting retrospective cohort studies or, for the cluster in Maryland, a case–control study (Table 2). Persons who attended the events associated with cases of cyclosporiasis were interviewed about symptoms and their consumption of food and beverages at the event. Univariate relative risks and odds ratios (for the Maryland cluster) were calculated for exposure variables, and two-tailed P values were computed with the chi-square test or, if appropriate, Fisher's exact test.

Sporadic cases were not associated with identified clusters, were laboratory confirmed, were characterized by the development of gastrointestinal symptoms during May 1 through August 31, and occurred in persons who had not traveled outside the United States or Canada during the two weeks before the onset of symptoms (the exposure period of interest).

Table 1. Number of Laboratory-Confirmed and Probable Cases of Cyclosporiasis in the United States and Canada in 1996, According to the Most Likely Site of the Acquisition of Infection.*

Location	Cluster-Associated Cases			Laboratory-Confirmed Sporadic Cases	Total	
	Laboratory-Confirmed	Probable†	Total		Laboratory Confirmed	Laboratory Confirmed + Probable
United States						
Colorado	4	10	14	0	4	14
Connecticut	0	0	0	38	38	38
District of Columbia	11	8	19	2	13	21
Florida	18	42	60	160	178	220
Georgia	0	0	0	5	5	5
Illinois	15	39	54	6	21	60
Iowa	0	0	0	1	1	1
Maine	0	0	0	2	2	2
Maryland	2	29	31	6	8	37
Massachusetts	21	67	88	82	103	170
New Hampshire	1	8	9	1	2	10
New Jersey	20	21	41	62	82	103
New York	29	87	116	191	220	307
Ohio	35	34	69	9	44	78
Pennsylvania	5	16	21	8	13	29
Rhode Island	0	0	0	9	9	9
South Carolina	11	25	36	7	18	43
Texas	22	27	49	48	70	97
Vermont	4	4	8	0	4	8
Virginia	1	15	16	1	2	17
Wisconsin	0	0	0	1	1	1
Subtotal	199	432	631	639	838	1270
Canada						
Ontario	36	55	91	98	134	189
Quebec	3	0	3	3	6	6
Subtotal	39	55	94	101	140	195
Total	238	487	725	740	978	1465

*Cases are categorized according to the most likely site of acquisition of infection rather than according to the place of residence.

†The number of cluster-associated probable cases equals the total number of cluster-associated cases minus the number of laboratory-confirmed cases. For 21 of the 52 clusters with probable cases (40.4 percent), the definition of infection was strict (minimal criteria, three or more loose or watery stools for three or more days); for the other clusters, less strict definitions were used.

TABLE 2. EVENTS ASSOCIATED WITH CLUSTERS OF CASES OF CYCLOSPORIASIS IN 1996, ACCORDING TO THE STATE OR PROVINCE IN THE UNITED STATES AND CANADA.*

LOCATION	EVENTS				MEDIAN ATTACK RATE†		MOST STRONGLY IMPLICATED BERRY ITEM CONTAINED ONLY RASPBERRIES‡	NO BERRIES BESIDES RASPBERRIES SERVED‡	P VALUE FOR ASSOCIATION OF BERRY ITEM WITH CYCLOSPORIASIS§			
	TOTAL NO. OF EVENTS	NO. WITH WELL-DOCUMENTED SOURCE DATA	DATES¶	TOTAL NO. OF ATTENDEES (MEDIAN % INTERVIEWED)‖	AMONG ALL ATTENDEES INTERVIEWED	AMONG THOSE WHO ATE BERRY-CONTAINING ITEM			<0.05	UNDEFINED	NOT DETERMINED	≥0.05
					percent				number of events			
United States												
Colorado	1	1	5/25	80 (42.5)	41.2	80.0	1	1	1	0	0	0
District of Columbia	2	1	5/28–6/1	64 (44.6)	76.2	93.3	0	0	1	0	1	0
Florida	9	6	5/5–6/14	108 (100)	66.7	100	4	2	3	1	0	5
Illinois	3	1	5/10–6/8	95 (100)	78.6	95.7	1	0	3	0	0	0
Maryland	1	0	5/18–6/1	200 (28.0)	55.4	81.0	1	0	1	0	0	0
Massachusetts	4	2	5/11–6/13	165 (87.4)	76.4	100	2	2	2	1	0	1
New Hampshire	1	0	6/1	40 (22.5)	100	ND**	0	0	0	0	1	0
New Jersey	2	1	5/25–6/1	122 (61.6)	42.7	53.2	0	0	1	0	1	0
New York	7	3	5/4–6/14	1292 (77.1)	58.9	85.0	3	2	5	0	1	1
Ohio	6	3	5/18–6/1	259 (74.4)	66.0	91.3	4	1	2	1	0	3
Pennsylvania	2	2	5/10	39 (98.4)	61.5	77.1	2	2	1	0	0	1
South Carolina	1	1	5/23	64 (100)	56.3	88.6	1	0	1	0	0	0
Texas	5	5	5/9–5/30	105 (100)	52.6	100	1	0	4	1	0	0
Vermont	2	1	5/20–5/23	14 (100)	75.0	80.0	1††	1††	0	1	0	1
Virginia	1	0	5/3	72 (93.1)	23.9	31.3	0	0	0	0	0	1
Canada												
Ontario	7	2	5/11–6/9	313 (80.0)	54.5	70.0‡‡	0	0‡‡	2	0	3	1‡‡
Quebec	1	0	6/5	3 (100)	100	100	0	0	0	1	0	0
Total	55	29	5/3–6/14	3035 (93.1)§§	56.3§§	93.3‡‡§§	21¶¶	11‡‡	27	6	7	14‡‡‖‖

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*See NAPS document no. 05398 for 5 pages of supplementary material. Order from NAPS, c/o Microfiche Publications, P.O. Box 3513, Grand Central Station, New York, NY 10163-3513. Remit in advance (in U.S. funds only) $11.65 for photocopies or $5 for microfiche. Outside the U.S., add postage of $4.50 for up to 20 pages, $5.50 for over 20 pages, or $1.50 for microfiche. There is a $15 invoicing charge on all orders filled before payment.

†The values are the medians of the event-specific rates, which are the percentages of persons in a particular category who were case patients (in the first subgroup the denominator includes all attendees interviewed, irrespective of exposure; in the second subgroup the denominator includes all persons who ate a berry item that contained or may have contained raspberries and was most strongly implicated). Attack rates were available for all events except one in the District of Columbia (for both subgroups), one in New Hampshire (for the second subgroup), one in New Jersey (for the second subgroup), one in New York (for both subgroups), and four in Ontario (for the second subgroup).

‡It is unclear whether raspberries were served at four events (if served, they were in fruit mixtures): one event in New Hampshire (some guests reported that raspberries were served), two events in Texas (Guatemalan raspberries were in the establishments on the days of the events and may have been served), and one event in Ontario (the fruit flan may have included raspberries).

§The four categories of P values are mutually exclusive. A P value was classified as undefined if a row or column total in the two by two table was zero and as not determined if a formal epidemiologic investigation of the exposures was not conducted

¶For each multiday event, the starting date is shown. In a case–control study of a cluster in Maryland (at an independent living facility), ill persons were questioned about the two-week period before the onset of illness and control subjects (well persons in the facility) were questioned about the period from May 18 to June 1.

‖Data provided are the total number of attendees for all events in a location (the number of attendees was approximated for 15 events) and the median event-specific interview rates (percentages of attendees who were interviewed)

**ND denotes not determined.

††Strawberries may have been served at this event but probably were not.

‡‡No data are provided for one event in Ontario because no raspberries were served; blackberries from Guatemala were served in a fruit mixture, but it is not known whether they were fresh.

§§The value is the median of the event-specific rate, not of the location-specific medians provided in this column

¶¶For 2 of the 21 events, consumption of the berry item that included only raspberries was highly correlated with consumption of one or more other items that included other berries.

‖‖The relative risks (an odds ratio for the Maryland event) for berry items of interest for 54 events at which raspberries were or could have been served included 16 values that were ≥2.0 (8 of which were ≥6.0), 6 that were <2.0, 19 that were infinite (attack rate >0 among exposed persons but 0 among those who were not exposed; no row or column total in the two by two table was zero), 6 that were undefined (a row or column total in the two by two table was zero), and 7 that were not determined (there was no formal epidemiologic investigation of the exposures)

Tracing of the Sources of the Raspberries and Environmental Investigation

To identify the sources of implicated raspberries, we obtained dates of purchase and shipment. We used airway bill numbers supplied by importers to identify shipments and exporters and then farms that contributed to shipments. A well-documented tracing of the source was one in which each step from consumers back to farms was confirmed verbally and in writing (e.g., through copies of invoices). We visited farms and exporters in Guatemala to investigate the ways in which raspberries were grown and handled. We also investigated the way in which berries were inspected in the Miami airport. The epidemiologic and source data provided here are those available to the CDC by October 31, 1996.

RESULTS

General Epidemiologic Investigation

A total of 1465 cases of cyclosporiasis — 725 cluster-associated cases (49.5 percent) and 740 sporadic cases (50.5 percent) — were reported by 20 states, the District of Columbia, and 2 provinces (Table 1). All sites were east of the Rocky Mountains except the one in Colorado. A little more than half the cases were in females (772, 52.7 percent), 41 (2.8 percent) were in children under 18 years of age, and 3 (0.2 percent) were in persons known to be infected with the human immunodeficiency virus. Twenty-two hospitalizations (1.5 percent of cases) but no deaths were reported.

Overall, 978 cases (66.8 percent) were confirmed by various laboratories. At the CDC, quality-control examination of stained slides of stool specimens from 324 persons reconfirmed 159 of 176 as positive (90.3 percent) and 145 of 148 as negative (98.0 percent). The CDC also demonstrated oocyst sporulation in specimens from 11 persons from five sites. Most laboratory-confirmed cases (>90 percent) were associated with diarrhea, loss of appetite and weight, and fatigue (Table 3).

Epidemiologic Investigation of Clusters of Cases

Fifty-five clusters of cases associated with attendance at a specific event were reported (Table 2). The events occurred from May 3 through June 14 (Fig. 1A); 22 (40.0 percent) were in private residences; 22 took place in restaurants, clubs, or hotels; and 11 (20.0 percent) occurred elsewhere. A total of 3035 persons attended (median, 28 per event; range, 2 to 1000), 1339 (44.1 percent) of whom were interviewed; of these, 772 had an event-associated illness, 725 (54.1 percent of 1339) were designated as case patients, and 238 (32.8 percent of 725) had laboratory-confirmed cases. The median event-specific attack rate among the persons interviewed was 56.3 percent (range, 19.0 to 100 percent; information was available for 53 events). Incubation periods for cases ranged from 1 to 14 days (by definition, <15); the median of the event-specific median incubation periods was 7 days.

The only type of exposure consistently associated with cyclosporiasis was the consumption of raspberries; they were definitely served at 50 events and may have been served at 4 events (Table 2). Whereas raspberries were definitely not served at only 1 event (an event in Ontario at which Guatemalan blackberries were included in a fruit mixture), strawberries, blackberries, and blueberries were not served at a minimum of 13 (23.6 percent), 30 (54.5 percent), and 32 (58.2 percent) events, respectively. Although investigations of three May events had initially implicated strawberries, on reevaluation of the menus raspberries either were included (at an event in Ontario) or may have been included (at two events in Texas) among the implicated berry items. For at least 10 and probably 11 (20.0 percent) of the 55 events, raspberries were the only berry served; for at least 3 other events, other berries but no strawberries were also served.

The median of the event-specific attack rates among persons who ate the berry items that contained or may have contained raspberries, with or without other berries, was 93.3 percent (range, 29.6 to 100 percent; information was available for 47

Table 3. Symptoms Associated with 760 Laboratory-Confirmed Cases of Cyclosporiasis in the United States and Canada in 1996.*

Symptom	No. with Symptom/ No. with Available Data (%)†
Diarrhea‡	750/759 (98.8)
Loss of appetite	471/507 (92.9)
Fatigue	608/658 (92.4)
Weight loss§	584/644 (90.7)
Abdominal bloating or gas	236/282 (83.7)
Abdominal cramps or pain	519/695 (74.7)
Nausea	509/713 (71.4)
Muscle, joint, or body aches	204/310 (65.8)
Fever¶	348/649 (53.6)
Chills	124/252 (49.2)
Headache	106/224 (47.3)
Constipation	47/148 (31.8)
Vomiting	187/697 (26.8)

*Data on symptoms were available for 760 case patients, including 643 with sporadic cases and 117 with cluster-associated cases. The median duration of illness was ≥14 days (range, 1 to 60) among 417 case patients for whom this information was available (at least 24 [5.8 percent] were still ill when interviewed); the duration of diarrheal illness was used for 202 case patients for whom the duration of the entire illness was unknown.

†The denominators for the various symptoms vary because not all sites collected data on all symptoms.

‡The median number of stools per day was 6 (range, 1 to 48) among the 536 case patients for whom this information was available. The median duration of diarrheal illness was 10 days (range, 1 to 60) among the 209 case patients for whom this information was available. Ten case patients noted bloody stools.

§The median weight loss was 3.6 kg (range, 0.9 to 18.2) among the 384 case patients for whom this information was available.

¶The median self-reported temperature was 38.3°C (range, 37.2° to 39.4°) among the 106 case patients for whom this information was available.

events). When we excluded from the 55 events the 1 event at which raspberries were definitely not served, the 6 events for which the P value was undefined, and the 7 events for which the P value was not determined, the associations between these berry items and cyclosporiasis were statistically significant ($P<0.05$) for 27 of the remaining 41 events (65.8 percent) (Table 2). When the events at which only mixtures of berries were served or the consumption of various berries was highly correlated were also excluded, raspberries could be specifically implicated in 10 events.

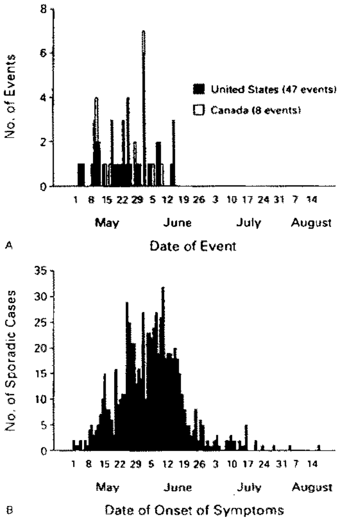

Figure 1. Dates of Events Associated with 55 Clusters of Cases of Cyclosporiasis (Panel A) and Dates of the Onset of Symptoms of 737 Laboratory-Confirmed Sporadic Cases of Cyclosporiasis (Panel B) in the United States and Canada in 1996.

In Panel A, the dates of events ranged from May 3 through June 14. For multiday events, the first day is indicated. For the cluster in Maryland, the first day of the two-week period about which control subjects in the case–control study were questioned is indicated (May 18).

In Panel B, the dates of the onset of symptoms ranged from May 1 through August 17. The dates were known or approximated for 737 of the 740 case patients who reportedly became ill on or after May 1; 50 percent became ill by June 5, and 90 percent by June 20. An additional 39 patients with possible cyclosporiasis were excluded from the investigation because of uncertainty about whether they became ill on or after May 1.

Raspberries were served fresh, except perhaps at two events (at which their status was unknown or they were stored briefly in a freezer). They reportedly had been rinsed at 33 of 41 events (80.5 percent) for which such information was available. Raspberries were used as garnishes (e.g., for a lemon tart) at 14 or more events, with an estimated median number of raspberries per serving of 2.5 (range, 1 to 7.5 for 7 events), and were included in sauces at 4 or more events, including 2 at which garnishes were used.

Sporadic Cases

The 740 sporadic cases occurred among persons whose median age was 49 years (range, 1 to 92; age was known for 717 case patients), were distributed approximately equally between the sexes (383 of 739 occurred in females; 51.8 percent), and developed from May 1 through August 17 (Fig. 1B). The proportions of sporadic cases in which fresh strawberries, raspberries, blueberries, and blackberries were reportedly eaten were 79.4 percent (501 of 631), 57.8 percent (365 of 632), 32.2 percent (138 of 429), and 19.3 percent (111 of 576), respectively. Among the 130 cases in which strawberries were not eaten, raspberries were eaten in 65 (50.0 percent); among the 267 cases in which raspberries were not eaten, strawberries were eaten in 200 (74.9 percent).

Tracing of Sources and Environmental Investigation

We attempted to trace the sources of raspberries for the 54 events at which raspberries were or may have been served. Those served at all 29 events for which we had well-documented data on the source (Fig. 2 and Table 2) either definitely were from Guatemala (21 events, 72.4 percent) or could have originated there (8 events, 27.6 percent, for which at least one of the raspberry shipments that could have been used came from Guatemala). The raspberries served at these events, which occurred from May 5 through June 14, were shipped from Guatemala from May 1 through June 5; seven exporters, of which A and B were the largest, shipped to the United States throughout this period.

The raspberries for 25 of the 29 events (86.2 percent) were traceable to one (vs. more than one) Guatemalan exporter per event: 18 of 25 (72.0 percent) to exporter A, 5 (20.0 percent) to exporter B, 1 (4.0 percent) to exporter C, and 1 (4.0 percent) to exporter D (Fig. 2). The raspberries at 11 of these 25 events (44.0 percent) were traceable to one (vs. more than one) shipment per event (median interval from shipment to consumption, 7 days; range, 3 to 15). Overall, the implicated raspberries for these 25 events could have been obtained from 39 shipments (May 1 through June 4) to eight importers. The ship-

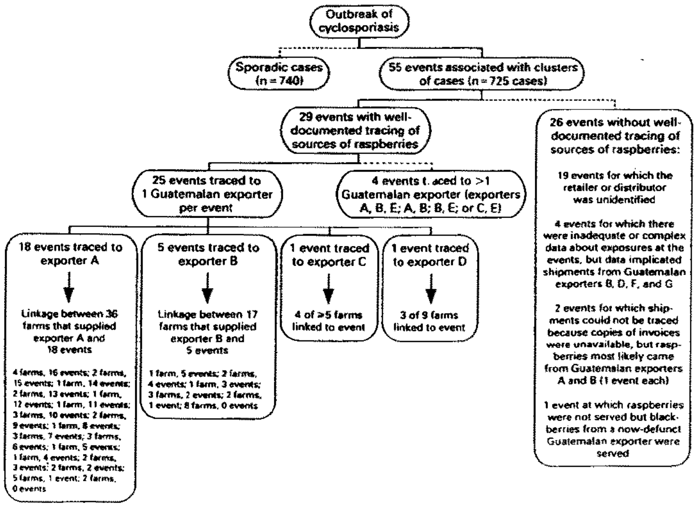
Outbreak of cyclosporiasis
Sporadic cases (n = 740)
55 events associated with clusters of cases (n = 725 cases)
29 events with well-documented tracing of sources of raspberries
26 events without well-documented tracing of sources of raspberries:
19 events for which the retailer or distributor was unidentified
4 events for which there were inadequate or complex data about exposures at the events, but data implicated shipments from Guatemalan exporters B, D, F, and G
2 events for which shipments could not be traced because copies of invoices were unavailable, but raspberries most likely came from Guatemalan exporters A and B (1 event each)
1 event at which raspberries were not served but blackberries from a now-defunct Guatemalan exporter were served
25 events traced to 1 Guatemalan exporter per event
4 events traced to >1 Guatemalan exporter (exporters A, B, E; A, B; B, E; or C, E)
18 events traced to exporter A
Linkage between 36 farms that supplied exporter A and 18 events
4 farms, 16 events; 2 farms, 15 events; 1 farm, 14 events; 2 farms, 13 events; 1 farm, 12 events; 1 farm, 11 events; 3 farms, 10 events; 2 farms, 9 events; 1 farm, 8 events; 3 farms, 7 events; 3 farms, 6 events; 1 farm, 5 events; 1 farm, 4 events; 2 farms, 3 events; 2 farms, 2 events; 5 farms, 1 event; 2 farms, 0 events
5 events traced to exporter B
Linkage between 17 farms that supplied exporter B and 5 events
1 farm, 5 events; 2 farms, 4 events; 1 farm, 3 events; 3 farms, 2 events; 2 farms, 1 event; 8 farms, 0 events
1 event traced to exporter C
4 of ≥5 farms linked to event
1 event traced to exporter D
3 of 9 farms linked to event

Figure 2. Flow Chart Tracing the Sources of Raspberries Served at Events Associated with Clusters of Cases of Cyclosporiasis in the United States and Canada in 1996.

With respect to the 25 events traced to one Guatemalan exporter per event, 2 events in Texas were included at which it is not certain that raspberries were served; Guatemalan raspberries were in the establishments on the days of the events. Exporter E, a possible supplier for three events, exported raspberries only from the one farm it owned. A farm was linked to an event if it contributed to a shipment of raspberries that could have been used at the event. For example, for exporter A, each of four farms could have been the source of raspberries served at each of 16 events (not necessarily the same 16 events for each farm). For the 18 events for which exporter A was the sole possible Guatemalan supplier, 27 shipments (of 92 from exporter A from May 1 to June 5, the period of interest) were potentially implicated, to which 34 farms contributed raspberries (of 36 farms that sold to exporter A throughout the period of interest). A median of 11 farms contributed to each shipment (range, 3 to 28), which contained a median of 854 kg of raspberries (range, 182 to 2467). For the five events for which exporter B was the sole possible Guatemalan supplier, 10 shipments (of 100 possible for exporter B during the period of interest) were potentially implicated, to which 9 farms contributed (of 17 that sold to exporter B throughout the period of interest). A median of 2 farms contributed to each shipment (range, 1 to 6), which contained a median of 624 kg of raspberries (range, 454 to 1342).

ments arrived on five airline carriers at four U.S. ports of entry: Miami (33 shipments, 84.6 percent), the District of Columbia (3, 7.7 percent), Houston (2, 5.1 percent), and Los Angeles (1, 2.6 percent). In Miami, which was the port of entry for at least one shipment per event for all events except one, shipments were inspected in four cargo-clearance areas. Because exporters typically combined raspberries from multiple farms in a shipment, even a well-documented tracing of the source could identify only a group of contributing farms (median, 10 farms per event; range, 2 to 30) rather than one source farm. However, as few as five farms — two for exporter A and one each for exporters B, C, and D — could have accounted for all 25 events (Fig. 2).

Thirty-four of the 36 farms that sold raspberries to exporter A throughout the period May 1 through June 5 were potential source farms for at least 1 of the 18 events linked solely to this exporter. Various combinations of 2 of the 34 farms could have accounted for all 18 events; each of 4 farms could have supplied raspberries for 16 of the 18 events (88.9 percent), and each of 2 other farms to 15 events (Fig. 2). The six most commonly implicated farms are in the same region of Guatemala, began harvesting simultaneously in 1996, and often had raspberries in the same shipments. Five of the farms obtained agricultural water from wells, which varied in construction, depth, and quality; two of the five farms also stored well water in reservoirs constructed of concrete blocks and covered with concrete. The sixth farm used river water.

Nine of the 17 farms that sold to exporter B were potential source farms for at least one of the five events linked solely to this exporter. One of these nine farms could have supplied raspberries to all five events. This farm, which is 25 km from the closest of the six most implicated farms that sold raspberries to exporter A, used well water, which also was stored in a mesh-covered, plastic-lined, dug reservoir.

Agricultural water on the seven most commonly implicated farms that sold raspberries to exporter A or B and on Guatemalan raspberry farms in general is filtered to remove debris but not microbes. In the late summer of 1996, testing of agricultural-water samples from the seven farms indicated at least intermittent bacterial contamination, including fecal coliforms or *Escherichia coli* (data not shown). To avoid direct contact between berries and water, ground-level drip irrigation is used (primarily during the dry season). However, agricultural water is also used to mix insecticides and fungicides that are sprayed directly onto raspberries, sometimes as late as the day they are picked. Berries are picked and sorted by hand, packed on the farms in plastic "clamshells," usually kept cool thereafter, and flown to the United States within 36 hours of picking.

DISCUSSION

Our investigation of a large outbreak of cyclosporiasis implicated Guatemalan raspberries. The strength of the investigation was in the collective evidence from clusters of cases associated with 55 events, at virtually all of which raspberries were served; hundreds of sporadic cases; and 29 events for which there was well-documented tracing of the sources of raspberries. We could not assess the true magnitude of the outbreak; most cases were probably undetected and unreported. For salmonellosis, a more familiar and easily diagnosed condition than cyclosporiasis, the number of cases reported to the CDC probably represents only 1 to 5 percent of all cases of infection in a year.[26] During routine testing for ova and parasites, stool specimens are not usually examined for cyclospora, and many laboratories do not yet have the expertise to identify it (CDC: unpublished data). Experienced personnel in a few sites were instrumental in detecting the outbreak of cyclosporiasis at its inception in May 1996, and subsequent media coverage most likely facilitated the identification of cases.

Data on the sporadic cases, like the data that we presented on the events, support the association between raspberries and cyclosporiasis. The dates of the events associated with the clustered cases and the dates of the onset of symptoms in sporadic cases were similarly distributed (Fig. 1), which suggests that both types of cases were attributable to the same type of exposure. Data from matched case–control studies of sporadic cases in New York City, New Jersey, and Florida demonstrated strong associations with raspberries[15,17,18] (and New York City Department of Health: unpublished data). Although not all case patients recalled eating raspberries, explanations include poor recall, which is expected for foods served as garnishes and in sauces, and other vehicles or modes of transmission for some background cases. A case–control study in Canada showed similarly strong, independent associations with both raspberries and strawberries,[19] but it was the latest case–control study conducted and may have had the most potential for recall bias.

The data tracing the sources of raspberries served at the events consistently implicated Guatemalan raspberries; this finding is especially noteworthy since raspberries from other countries were readily available during the outbreak period. In April, May, June, and July 1996, Guatemalan raspberries represented only 3.8 percent (14,000 of 368,000 kg), 19.8 percent (109,000 of 550,000 kg), 8.7 percent (155,000 of 1,786,000 kg), and 5.1 percent (27,000 of 532,000 kg), respectively, of fresh raspberries (domestic and imported) shipped within the United States (figures calculated on the basis of government data[27-29]). For example, in May 1996, only 36.6 percent and 37.5 percent of raspberries at market sites in New York City and Newark and in Baltimore and the District of Columbia, respectively, were grown in Guatemala; for Los Angeles and for San Francisco and Oakland, western sites that did not report cases, the respective percentages were 6.7 and 5.3.

Given that there were many differences in various aspects of the distribution systems for the implicated raspberries, simultaneous and persistent contamination on multiple farms is the most likely explanation for the outbreak. We do not know whether the contaminating oocysts came from humans or animals. Likewise, we do not know whether the oocysts were unsporulated (e.g., on workers' hands), in which case they would have required at least several days to sporulate, or had already sporulated (e.g., in soil or water). The prevalence of human cyclospora infection in Guatemala is being investigated by the CDC. Despite some suggestive evidence,[9,11,30-32] to date no animals, including chickens and other birds, have been identified as reservoirs of infection for cyclospora isolates that infect humans.

Postulating a role for contaminated water is appealing because waterborne transmission of cyclospora has been implicated previously.[3,11,33] One hypothesis is that raspberries became contaminated through spraying with insecticides and fungicides that had been mixed with contaminated water. Although we have not determined how water supplies on different farms could have become contaminated with oocysts during the same period, many water supplies were vulnerable to contamination because, for example, they were suboptimally constructed or maintained wells near deep pit latrines or seepage pits. They may have been particularly vulnerable during the rainy season (e.g., from surface-water runoff), which is when the 1996 outbreak occurred. No oocysts were found in samples of water and raspberries that were tested (data not shown), but the samples were obtained after the outbreak period, and the testing methods are insensitive. Once contaminated, by whatever means, fresh raspberries may remain contaminated until eaten because they are too fragile and replete with crevices[34] to be washed thoroughly. The high attack rates noted for most events, sometimes despite the consumption of only a few raspberries, suggest that the infectious dose of oocysts is low or the number of oocysts per berry was high, or both.

Although the mode of contamination remains unclear, our ability to pursue the investigation to the source of the raspberries resulted from the cooperation of the Guatemalan berry industry. The industry is now implementing a Hazard Analysis and Critical Control Point system; in such systems, selected points in production at which preventive and control measures can minimize or eliminate hazards are closely monitored.[35,36] We have recommended that potable water (e.g., water from a properly constructed and monitored deep well or water treated in ways that eliminate chlorine-resistant cyclospora oocysts) be used for drinking, hand washing, cleaning surfaces that touch berries, and mixing substances sprayed onto berries. Provision of better sanitary facilities for workers will decrease the potential for direct or indirect contamination of berries. Efforts to decrease the risk of cross-contamination should focus on the identification of the types of surfaces and cleaning solutions to use where berries are sorted and inspected. The effect of gamma irradiation on cyclospora oocysts is being investigated (Dubey JP: personal communication). Investigations of the source of the berries would have been easier if clamshell containers and invoices had been identified according to the source farm (e.g., with bar codes).

In summary, cyclospora has now been established to be a foodborne pathogen. This outbreak is a reminder that our supply of fresh produce has become increasingly international[37-39] and underscores the need to identify and investigate foodborne outbreaks promptly, to consider that a local cluster of cases could be part of a widespread outbreak, and to pursue investigations to the source of the implicated vehicle.[39] For imported vehicles, international collaboration is critical to the success of the investigation and to the identification of appropriate measures of prevention and control.

APPENDIX

The Cyclospora Working Group included the following (asterisks denote members of the Epidemic Intelligence Service, Epidemiology Program Office, CDC): California Department of Health Services, Food and Drug Branch — J. Farrar and S. Richardson, Jr.; Connecticut Department of Public Health and Addiction Services — R. Nelson; District of Columbia Department of Health — M. Fletcher and M. Levy; Florida: Florida Department of Health — D. Katz,* and Palm Beach County Health Department — S. Kumar, J. Malecki, and M. Lowdermilk; Illinois: Lake County Health Department — L. Mackey and J. Bell; Maryland: Maryland Department of Health and Mental Hygiene — D. Portesi, and Montgomery County Department of Health and Human Services — C. Lacey; Massachusetts: Massachusetts Department of Public Health — L. Letendre, D. Hamlin, and R. Knowlton, and Boston Department of Health and Hospitals — A. Barry; New Jersey Department of Health and Senior Services — D. Chew,* L. Finelli, and C. Genese; New York: New York City Department of Health — J. Miller and M. Layton, and New York State Department of Health — J. Guzewich; Ohio Department of Health — E. Salehi; Pennsylvania Department of Health — A. Weltman; South Carolina Department of Health and Environmental Control — V. Caceres* and R. Ball; Texas: Texas Department of Health — B. Barnett,* K. Hendricks, and J. Taylor, and Houston Department of Health and Human Services — R. Bell; Vermont Department of Health — S. Schoenfeld; Food Safety Consultation and Training — F. Bryan; Canada: Health Canada — S. Neamatullah and D. Werker, North York Public Health Department — D. Manuel, Ontario Ministry of Health — C. Le Ber, Montreal Children's Hospital — M. Arrieta, and Agriculture and Agri-Food Canada — D. Morrison; Medical Entomology Research and Training Unit, Guatemala — R. Klein; National Center for Infectious Diseases, CDC: Division of Parasitic Diseases — S. Wahlquist, E. Alfano, M. Eberhard, M. Arrowood, K. Hannak-Donaldson, M. Beach,* M. Kramer,* and A. Hightower, Division of Bacterial and Mycotic Diseases — D. Swerdlow, J. Winickoff, and R. Shapiro,* and Epidemiology Program Office — M. Messonnier.

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ment of Public Health — M. Erme, City of Cleveland, Department of Public Health — D. Willis, Cuyahoga County Board of Health — H. Scaife, Franklin County Board of Health — J. Stapleton, Lakewood Division of Health — E. Gorski, Mansfield-Richland County Health Department — G. Myers, Summit County Board of Health — G. Salem, and Ohio Department of Health — L. McAllister; Pennsylvania: Montgomery County Department of Health — C. Levin, and Pennsylvania Department of Health — M. Nygard; State of Rhode Island and Providence Plantations Department of Health — U. Bandy; South Carolina Department of Health and Environmental Control — S. Somerfeldt, L. Mackey, S. Nichols, A. Reddick, and M. Turner; Texas: Houston Department of Health and Human Services, University of Texas School of Public Health at Houston, Texas Department of Health, Dallas County Health Department, and Exxon Company, USA — E. Lawhorn; Vermont Department of Health — K. Munnett and R. O'Grady; Virginia Department of Health, Office of Epidemiology; George Washington University Hospital, Department of Microbiology — J. Keiser, E. Palmanis, and W. Carlton; Canada: North York Public Health Department — R. Shahin and the staff of the Communicable Diseases Division, Toronto Hospital — J. Keystone and D. Raymond, Ontario Ministry of Health — M. Brodsky and T. Scholten, and Montreal General Hospital — B. Ward; Food and Drug Administration: L. Solorzano; National Center for Infectious Diseases, CDC: Division of Parasitic Diseases — D. Juranek, S. Binder, T. Navin, E. Kovacs-Nace, J. Roberts, M. Hurd, M. Bartlett, and D. Colley, Division of Bacterial and Mycotic Diseases — R. Tauxe, and the Epidemiology Program Office — W. MacKenzie.

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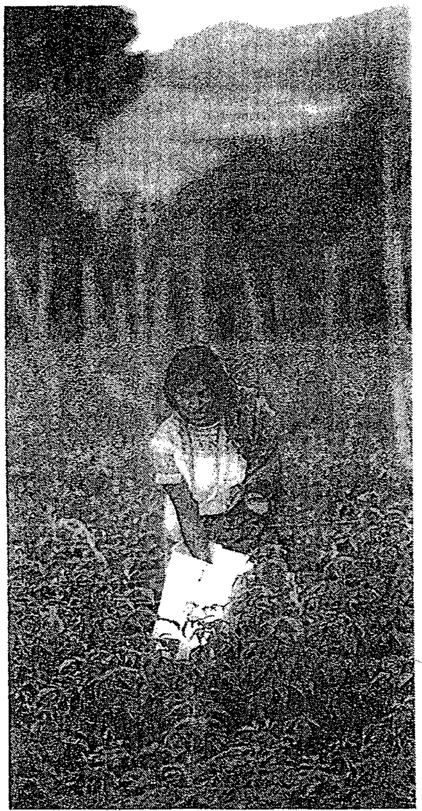
ATTACHMENT E

The New York Times

MONDAY, SEPTEMBER 29, 1997

Imports Swamp U.S. Food-Safety Efforts



Nancy McGuirr for The New York Times

A parasite rarely seen in this country has been traced to raspberries from Guatemalan farms like the one where this woman works.

By **JEFF GERTH**
and **TIM WEINER**

WASHINGTON, Sept. 28 — Since the 1980's, food imports to the United States have doubled. But Federal inspections of those imports by the Food and Drug Administration have dropped to less than half what they were five years ago.

Now, public-health scientists say they are seeing more and more outbreaks of disease linked to imported food, particularly fresh fruit and vegetables.

These are known to have sickened thousands of Americans, and those reported cases are a small fraction of the actual number of people made ill, according to scientists at the Centers for Disease Control and Prevention in Atlanta.

The scientists' list of outbreaks in the 1990's implicates imported foods — including raspberries from Guatemala and carrots from Peru, strawberries, scallions and cantaloupes from Mexico; coconut milk from Thailand, canned mushrooms from China; an Israeli snack food, and a multinational batch of alfalfa sprouts — in a variety of infectious diseases

TAINTED IMPORTS

A special report

The increase in imports has strained the nation's food-safety system, said Dr David A Kessler, the Food and Drug Administration commissioner from 1990 through February 1997 "We built a system back 100 years ago that served us very well for a world within our borders," he said in an interview. "We didn't build a system for the global marketplace."

Most of the food imported to the United States is wholesome. Consumers, knowing that fresh produce is good for their health, can now buy reasonably priced fruits and vegetables imported from around the world, regardless of the season, and without ill effect.

But the illnesses that have been

Continued on Page A10

More
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Markets

he amount of fruits nd vegetables nported to the nited States has sen in recent years, lthough tests of nported foods by the .D.A. have been cut early in half.

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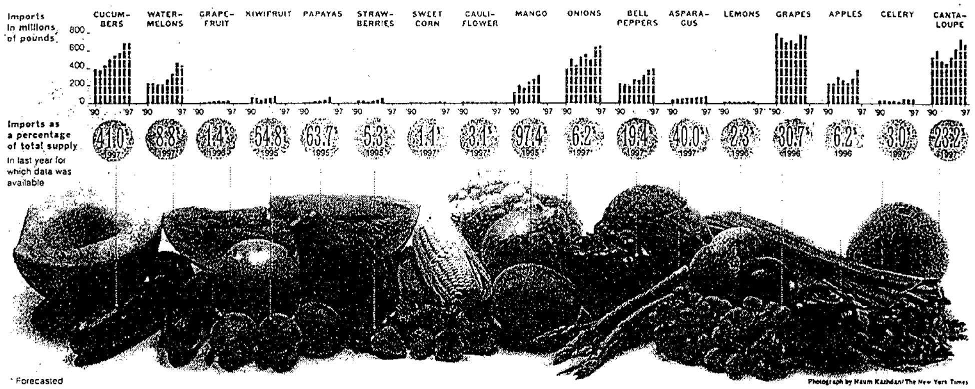


urce: Agriculture Department * Forecasted

Photograph by Naum Kazhdan/The New York Times

U.S. Food-Safety System Swamped by Booming Global Imports

imported along with some of the produce are an unintended byproduct of the boom in international trade — a boom long advocated by the Reagan, Bush and Clinton Administrations as crucial to economic growth.

There is "a tension between the two goals of safety and trade," said Mickey Kantor, President Clinton's first trade representative, who helped push global trade to the top of Mr. Clinton's agenda. "You want to open markets but not lower standards. And that's easy to say, but very, very difficult to carry out."

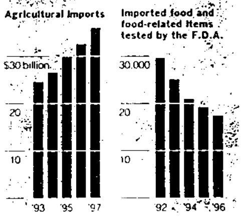
Scientists are recognizing that "free trade may present problems that are associated with food poisoning," said Dr. Marguerite A. Neill, an infectious disease specialist and a member of a Federal advisory panel drafting new food-safety standards. These problems cut both ways: radish sprouts from Oregon seeds sickened people in Japan in March, and South Korea said it detected E. coli bacteria in a shipment of frozen United States beef last week.

The problems imports may pose for American consumers include polluted water used to grow food in third-world nations, faulty safety systems in countries where the foods are produced, and a lack of natural immunity to exotic microbes rarely seen in this country. "Certain viruses, bacteria and parasites may be posing a unique problem in the U.S. because we haven't tended to be exposed to them," Dr. Neill said.

BY THE NUMBERS

More Imports, Fewer Tests

Food imports into the United States have risen while the F.D.A. has reduced the number of imports it examines.



Dr. Yasmine Motarjemi, a World Health Organization food-safety scientist, said the organization also believed that global trade "brings new pathogens into countries which are not immune."

Those problems were foreseeable — and foreseen.

In 1994, a Centers for Disease Control report said, "As trade and economic developments like Nafta take place, the globalization of food supplies is likely to have an increasing impact on food-borne illnesses."

In 1993, the Food and Drug Administration, in a memorandum citing "enormous inefficiencies in the current food-protection system" and the "ever-increasing challenges" posed by rapidly growing imports, asked the Clinton Administration for legislation giving it power to bar all food — including fruits, grains, vegetables and fish — imported from any country with an inferior food-safety system.

The Department of Agriculture has such authority over imported meat and poultry. But the F.D.A. never acquired that power though legislation or executive order.

Dr. Kessler said in an interview that he had told the Bush and Clinton Administrations that the safety system for imported food was inadequate and outdated.

"How is it physically possible to insure the safety of imported food?" he said. "You don't have police power throughout the world. Inspecting at the border has a limited value. You're left with real risks."

Now these risks figure in the political debate about free trade.

The Clinton Administration wants the power to sign new free-trade pacts without Congress's changing the language of those agreements. Opponents of this "fast track" authority raise the food-safety flag. Some food growers say that the risks from imports are insignificant, and that the C.D.C. exaggerates them.

The C.D.C. says diseases borne by domestic and foreign foods kill thousands of Americans and sicken millions, perhaps tens of millions, every year — mostly the very young, the very old and the very ill. Its scientists say almost none of those cases are ever traced back to their cause. As a result, they say, they lack the data to show how many people get sick from imported food, and whether that food is safer or less safe than domestic food.

Both sides in the fast track debate use the Centers for Disease Control's data to make their cases — and both sides mischaracterize what the data show, according to the scientists.

Now the Administration is preparing a proposal to address the problems posed by imported food — nine months after announcing a sweeping food-safety initiative that largely ignored them, and days after a bill to revamp the Food and Drug Administration was passed by the Senate.

The Food Chain

Modern-Day Travels Of Tainted Products

The United States has its own food-safety problems at home. Urgent questions about the integrity of America's food supply were raised when three American children died and 144 people were hospitalized after eating fast-food hamburgers in 1993. A reminder of the problem came this summer, when tainted hamburger meat from a Nebraska plant made 16 people sick.

But this spring and last, in an outbreak that attracted less attention, tainted raspberries from Guatemala made thousands of Americans sick. They were victims of a nearly invisible, dimly understood parasite called cyclospora, a species almost never seen in the United States before 1996.

To know the story of raspberries and cyclospora, Dr. Michael T. Osterholm, one of the nation's leading epidemiologists, wrote recently, "is to know food-borne disease in the modern world."

Not a single raspberry grew in Guatemala a decade ago. They grow today because the United States helped introduce them.

In the 1980's, during the height of the Guatemalan Army's campaign against leftist guerrillas, the United States Agency for International Development tried to win over the peasants by introducing them to the riches of global trade. Spurred by the Reagan Administration's Caribbean Basin Initiative, a 1983 free-trade measure that cut or eliminated tariffs on imports, the agency spent tens of millions of dollars promoting "nontraditional" agriculture in Guatemala.

It persuaded rural Guatemalans to switch from planting corn and beans for themselves to growing exotic crops for North Americans. It financed Guatemalan exporters and American importers who bring raspberries and other produce to the United States.

The raspberry trade exploded two years ago. Guatemala shipped less than 4,000 pounds of raspberries to the United States in 1992 — and about 700,000 pounds in 1996. The growers timed their first harvest of 1996 for late April and early May, when they would have the United States market almost completely to themselves.

But every April and May, when the spring rains come to the highlands, thousands of Guatemalans fall ill. They think something in the water flowing from the mountains makes them sick. And when the raspberries came to the United States in spring 1996, thousands of Americans fell ill as well. Many experienced weeks of misery — debilitating diarrhea severe cramps, chills, fever, nausea, weight loss, depression.

The Centers for Disease Control's scientists never found cyclospora on the raspberries, but they found it in the stools of the Americans who ate them. And they are fairly certain that the parasite lay hiding in the water in Guatemala — the water with which the berries were sprayed and irrigated just before they were picked, shipped and eaten fresh and raw days later in the United States

The case underscores the C.D.C.'s recen warning that "improving the microbiologica safety of drinking water and food production" overseas is crucial "to insure the safety of the increasing amounts of food imported to the United States."

After that experience, American scientist and Guatemalan growers, working together did everything they could to prevent anothe outbreak. But when this spring came, happened again: Hundreds, perhaps thousands, of Americans who ate Guatemala raspberries fell sick.

The cyclospora case is now the bigges outbreak of food-borne disease in the Unite States in years. The Centers for Diseas Control count at least 2,300 people sickene this year and last. They are "the tip of th iceberg, and we don't know how big th iceberg is," said Dr. Barbara Herwaldt of th

C.D.C. The Centers for Disease Control still know little about the parasite. But they established this spring that cyclospora is a common cause of diarrhea in Guatemalan children, and is still present in the water that runs through the highlands. The C.D.C. has shown that a polluted stream in a third world field can spawn a mysterious bug that can sicken a diner in midtown Manhattan.

"We eat out of everybody else's garden now," said Dr. Dan Colley, director of the Centers for Disease Control's division of parasitic diseases. And on an increasingly crowded planet, not everyone's garden is well kept.

When cyclospora struck in the United States again this spring, Guatemalan berry growers acted swiftly. First, they voluntarily suspended their shipments. Then they kicked the C.D.C.'s field investigator off their farms. Then they denounced the American scientists as snipers fighting a trade war on behalf of the growers' California competitors.

Roberto Castenãda, vice president of the Guatemalan Berries Commission, said in an interview: "Last year the guerrillas were in the fields asking my workers about their conditions, asking, 'Do you have bathrooms?' And this year, it was the C.D.C. The C.D.C. is killing us. They kill us every time they open their mouths."

Gabriel Biguria, a former president of Gexpront, the Guatemalan agricultural export group, said his country was the victim of an unfair trade practice.

"Cyclospora?" he said. "They can't find it. We find a tremendous possibility that people in California are using this as a very dangerous tool for protectionism. Protectionist forces find bugs or whatever to protect their market. It's a commercial war."

This dispute illustrates how science and politics collide in the arena of trade.

Some of the biggest food-trade fights have centered on the safety of American products. European nations did not want hormone-injected beef or chlorine-rinsed chicken. So far, the United States has won those cases. But now the United States sometimes finds itself on the other side of the fence, fighting with trading partners about the safety standards for their imports.

"Where we see a safety issue, they see a trade issue," said Dr. I. Kaye Wachsmuth, a leading Federal food-safety official.

The Inspectors

Import-Ban Power For the F.D.A.

Things were simpler when most of the food Americans ate was grown near their homes. Traditionally, food illness came from undercooked or mishandled domestic meat and poultry. Today, people depend more on global trade to satisfy their hunger.

"Go to a restaurant and take a look at your supper," said Dr. Robert Tauxe, chief of the food-borne and diarrheal disease branch at the Centers for Disease Control. "How many different continents are on your plate?"

The food chain that fills those plates has become unimaginably intricate.

For example, alfalfa sprouts gave salmonella to hundreds of people in 24 states this year and last. The seeds for those sprouts were bought from Uganda and Pakistan, among other nations, shipped through the Netherlands, flown into New York and trucked around the United States, Dr. Tauxe said.

Previously unknown pathogens are being discovered years after they arrive in the United States. Take the case of the Peruvian carrots, which took years to break.

In a coming issue of the Journal of Infectious Diseases, Dr. Osterholm and his colleagues will report their discovery of a new strain of E. coli bacteria, linked to a shipment of carrots from Peru. It took them six years to connect the new strain to a 1991 outbreak at a Minneapolis convention.

Most of the data on food-borne disease come from a relatively small number of outbreaks at big gatherings — conventions, restaurants and receptions. Most cases are never reported at all, said Dr. Osterholm, Minnesota's chief epidemiologist.

"If you get an outbreak of 500 people in a state, but no more than a few in any one household, you'll never pick it up," he said.

Because one percent or less of the actual number of outbreaks are reported, analyzed, identified and successfully traced back to the source, the C.D.C. says, its scientists cannot identify the causes of a great majority of food-borne diseases.

International food-borne outbreaks, said Dr. Colley of the Centers for Disease Control, are increasing and "can be expected to worsen as the world moves toward a global food economy."

Detecting microbes at the border is about as effective as detecting illegal drugs.

The Food and Drug Administration's inspectors test an ever-dwindling fraction of the 30 billion tons of food now imported into the United States. The responsibilities of individual inspectors have increased, but their resources have dwindled. They sampled 17,000 food items in 1996, less than one percent of 2.2 million food shipments, down from 30,000 samples, or about 3 percent of 1.1 million shipments, in 1992.

A more fundamental defense — insuring the safety of food at its source — does not exist. The F.D.A.'s inspectors can seize suspect imports, but they lack the power to automatically bar imported food just because it comes from a country with an inferior food-safety system.

Congress has never granted them that power. The White House has never publicly asked for it — until now, as it seeks fast track authority for trade pacts that is being seriously challenged in Congress over food-safety issues. The Administration plans to announce a proposal seeking to give the Food and Drug Administration the new powers this week.

The need has been apparent for years, Federal food-safety officials said. They cited the case of the tainted coconut milk from Thailand. In 1991, frozen coconut milk processed at a Bangkok plant, and exported by a Thai trading company to the United States, set off an outbreak of cholera. The life-threatening disease was thought to have been eradicated in this country.

"The Thai authorities were unaware of the existence of the plant," Dr. Tauxe said. "It was unlicensed, uninspected, unregulated."

Nor is it clear that the new powers the White House is planning to seek would have prevented the outbreak.

"I can't imagine an F.D.A. inspector in every country overseas," said Peggy Foegeding, a principal author of a landmark 1994 study on food-borne pathogens.

The United States is second to none at stopping food-borne disease after it breaks out. The Clinton Administration says it will lift up public-health and food-safety standards around the world until they meet those of the United States, in order to insure the safety of imported food.

But the United States' public-health systems today "cannot properly identify, track and control food-related illness, or prevent, to the extent possible, future cases from occurring," said a Federal report published in May as part of a food-safety initiative now nearing passage in Congress

Nancy McGirr for The New York Times

TAINTED FRUIT Raspberries from Guatemala have made thousands of Americans ill. Mayan women weeded a raspberry field recently

The Safety Net

Eroding Resources For Surveillance

Some Federal agencies are helping their foreign counterparts improve their public health systems. But "the United States cannot really build public health structures for the world," said Kerri-Ann Jones, a top White House science official.

The Clinton Administration says it wants more surveillance, more research, more F.D.A. inspectors. But "Federal budget constraints will likely prohibit significant funding increases in the future" for the F.D.A., said the food safety initiative report published in May.

Many state health departments are overburdened and underfinanced, in part because of the AIDS crisis. Twelve states have no system for reporting food-borne disease, largely because of budget restrictions, public health officials say.

And many countries are reducing their own disease-surveillance abilities. "Economic globalization has also increased the need for governmental budget austerity," and countries around the world are cutting spending on public health to streamline their economies, according to a coming study by World Health Organization officials.

Scientists have fought new diseases spread by trade, travel and technology before. One night in 1849, a British doctor, John Snow, had a brainstorm. Having realized that cholera was spread by contaminated water, he ripped the handle off a water pump in a London slum and stopped an epidemic.

Global trade, the gigantic pump bringing the essentials and luxuries of life, and the small but rising threat of disease pose more intricate challenges for scientists.

Dr. Kessler and other prominent scientists, while acknowledging the problems with domestic food, said those challenges could be summarized by two questions:

As the world's nations become more intertwined, interdependent and intensely competitive, will the rest of the world's standards become more like those of the United States, with its relatively safe water, sound hygiene and state-of-the-art science? Or will the United States, despite its high standards, become more vulnerable to the rest of the world's microbes?

"The challenge for the United States," Dr. Kessler said, "is to raise everyone else's standards."

ATTACHMENT F

MEDIA RELEASE

TORONTO
Public Health

June 11, 1998

CYCLOSPORA INFECTION

Toronto Public Health is investigating seven outbreaks of Cyclospora infection related to food eaten between May 7 and 15. Cyclospora infection is caused by a parasite which may be transmitted by ingestion of contaminated food or water.

Two other outbreaks of the infection have been reported in Ontario.

Cyclospora infection typically causes watery diarrhea, loss of appetite and weight loss, bloating, increased flatus, stomach cramps, nausea, vomiting, muscle aches, low-grade fever and fatigue. This infection is easily treated with an antibiotic. If untreated, the illness may last for a few days to a month or longer. People who are not treated may get a relapse of the disease. Symptoms of the disease usually appear within 7 to 10 days of eating the contaminated food, but may occur earlier or later.

More than 60 people have become ill with Cyclospora after attending various events in the City of Toronto. People who have the above symptoms should contact their doctor.

Toronto Public Health is collaborating with the Ministry of Health, and other health officials to find the source of the outbreak. Cyclospora infection has been connected to a variety of fresh produce in the past. Ontario had outbreaks of Cyclospora infection in the spring of 1996 and 1997.

Although Cyclospora may not be entirely eliminated by washing, it is always prudent to thoroughly wash all produce.

-30-

For more information:
Jackie Smith, Communications Manager, 392-1560 ext. 8-7068
Dr. Barbara Yaffe, Associate Medical Officer of Health, 392-7401
Ministry of Health, Communications and Information, 327-4343

TORONTO

Public Health
277 Victoria Street, 5th Floor
Toronto, Ontario
Canada M5B 1W1
www.city.toronto.on.ca
Tel: 416-392-7407
Fax: 416-392-0713

MEDIA UPDATE:

June 19, 1998

CYCLOSPORA OUTBREAK

The following information is provided as updating information on the cyclospora outbreak. No new information is expected until Monday.

The Cyclospora outbreak is one outbreak with 13 confirmed or suspected clusters; i.e. there were 13 events, such as private parties, weddings, large functions, where people became ill. These events took place between May 7 and 23.

Totals clusters and locations of clusters:
Total - 13, (11 confirmed by laboratory testing and two suspected):
Breakdown: 8
- Toronto 8, and one suspected.
- Simcoe County, one and one suspected.
- York Region, one.
- Lindsay, one.

Number of people ill:
About 250 people have confirmed or suspected Cylospora infection; 160 of these are related to the clusters and 88 are individuals who became ill, but as far as we know were not at the 13 events.

Number of laboratory confirmed cases - more than 80:

Source of outbreak:
The source of the outbreak is still unknown. However, a common item in all the clusters is imported raspberries. The Canadian Food Inspection Agency has assured us that raspberries currently for sale in Ontario are from the United States and Canada. To our knowledge, raspberries from the U.S. and Canada have never been implicated in a cyclospora outbreak.

The investigation:
Health officials are interviewing more than 700 people who attended the various events where people became ill. We are looking at what they ate and where the food came from.

Current risk:
There is no reason to believe there is any risk with berries currently on the market. These are grown in Canada and the United States.

Next media update:
Monday June 22.

For more information call Jackie Smith at 392-1560 ext 87068

TORONTO

Public Health
277 Victoria Street, 5th Floor
Toronto, Ontario
Canada M5B 1W1
www.city.toronto.on.ca
Tel: 416-392-7407
Fax: 416-392-0713

MEDIA UPDATE

CYCLOSPORA OUTBREAK

June 23, 1998

Dr. Barbara Yaffe, Associate Medical Officer of Health, today briefed the Board of Health on the Cyclospora outbreak.

The Board asked the Public Health department to provide a detailed report on the outbreak when the current investigation is complete, along with recommendations for the labelling of fresh produce with the name of the country or place of origin. The Board also asked the department to consider recommending a ban on the importation of Guatemalan raspberries to Canada, as is currently in place in the United States, if they are found to be the source of the current outbreak.

The Cyclospora outbreak is one outbreak with 18 confirmed or suspected clusters; i.e. there were 18 events, such as private parties, weddings, large functions, where people became ill. These events took place between May 7 and 23.

Number of people ill:

About 284 people have confirmed or suspected Cylospora infection; 170 of these are related to the clusters and 114 are individuals who became ill, but as far as we know were not at the 18 events.

Number of laboratory confirmed cases - more than 150:

Breakdown on clusters and locations of clusters:

- Toronto 8, and 5 suspected.
- Simcoe County, two confirmed.
- York Region, one and one suspected.
- Lindsay, one.

Source of outbreak:

Toronto Public Health is working with local health units, Health Canada, the Ontario Ministry of Health, the Canadian Food Inspection Agency and the Centers for Disease Control in Atlanta to find the source of the outbreak. However, a common food item in all of the clusters is imported raspberries. Raspberries eaten at several of the events investigated so far are believed to have originated in Guatemala. The Canadian Food Inspection Agency has assured Public Health that raspberries currently for sale in Ontario are from the United States and Canada. To our knowledge, raspberries from the U.S. and Canada have never been implicated in a Cyclospora outbreak.

The Investigation:

We have interviewed more than 300 of approximately 700 people who attended the various events where people became ill to find out what they ate and where the food came from.

Current risk:

There is no reason to believe there is any risk with berries now on the market, which are grown in Canada and the United States.

For information on the investigation call:
Jackie Smith, Communications Manager at 392-1560 ext 87068

For information on Board of Health recommendations call:

ATTACHMENT G

Risk Analysis, Vol. 16, No. 6, 1996

A Conceptual Framework to Assess the Risks of Human Disease Following Exposure to Pathogens

ILSI Risk Science Institute Pathogen Risk Assessment Working Group[1-3]

Received March 22, 1996; revised July 10, 1996

Currently, risk assessments of the potential human health effects associated with exposure to pathogens are utilizing the conceptual framework that was developed to assess risks associated with chemical exposures. However, the applicability of the chemical framework is problematic due to many issues that are unique to assessing risks associated with pathogens. These include, but are not limited to, an assessment of pathogen/host interactions, consideration of secondary spread, consideration of short- and long-term immunity, and an assessment of conditions that allow the microorganism to propagate. To address this concern, a working group was convened to develop a conceptual framework to assess the risks of human disease associated with exposure to pathogenic microorganisms. The framework that was developed consists of three phases: problem formulation, analysis (which includes characterization of exposure and human health effects), and risk characterization. The framework emphasizes the dynamic and iterative nature of the risk assessment process, and allows wide latitude for planning and conducting risk assessments in diverse situations, each based on the common principles discussed in the framework.

KEY WORDS: Pathogen risk assessment; microbial; framework.

1. INTRODUCTION

The potential for human disease associated with exposure to pathogenic microorganisms is a growing public health concern. This concern has been prompted in part by several recent outbreaks of cryptosporidiosis in the United States, the recent cholera epidemic in South America, outbreaks of *Cyclospora* sp. and *E. coli*, as

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[1] Washington, D.C.

[2] Working group members include: Ronald Brown, U.S. Food & Drug Administration, Rockville, Maryland; Gunther Craun, Global Consulting Environmental Health, Radford, Virginia; Alfred Dufour, U.S. Environmental Protection Agency, Cincinnati, Ohio; Joe Eisenberg, University of California at Berkeley, Berkeley, California; Jeffery Foran, ILSI Risk Science Institute, Washington, D.C.; Charles Gaunt, University of Texas Health Science Center, San Antonio, Texas; Charles Gerba, University of Arizona, Tucson, Arizona; Charles Haas, Drexel University, Philadelphia, Pennsylvania; Anita Highsmith, Centers for Disease Control and Prevention, Atlanta, Georgia; Robert Irbe, the Nutrasweet Company, Mt. Prospect, Illinois; Päivi Julkunen, The Coca-Cola Company, Atlanta, Georgia; Dennis Juranek, Centers for Disease Control and Prevention, Atlanta, Georgia; Mark LeChevallier, American Water Works Association Service Company, Voorhees, New Jersey; Myron Levine, University of Maryland at Baltimore, Baltimore, Maryland; Bruce Macler, U.S. Environmental Protection Agency, San Francisco, California; Patricia Murphy, U.S. Environmental Protection Agency, Cincinnati, Ohio; Pierre Payment, Université du Québec, Québec, Canada; Fred Pfaender, University of North Carolina, Chapel Hill, North Carolina; Stig Regli, U.S. Environmental Protection Agency, Washington, D.C.; Alan Roberson, American Water Works Association, Washington, D.C.; Joan Rose, University of Florida, St. Petersburg, Florida; Stephen Schaub, U.S. Environmental Protection Agency, Washington, D.C.; Gilbert Schiff, James N. Gamble Institute of Medical Research, Cincinnati, Ohio; Jennifer Seed, ILSI Risk Science Institute, Washington, D.C.; Charlotte Smith, Charlotte Smith and Associates, Venice, Florida; Mark Sobsey, University of North Carolina, Chapel Hill, North Carolina; Robert Spear, University of California at Berkeley, Berkeley, California; Isabel Walls, National Food Processors Association, Washington, D.C.

[3] All correspondence should be addressed to Dr. Jeffery Foran, Executive Director, ILSI Risk Science Institute, 1126 Sixteenth Street, N.W., Washington, D.C. 20036.

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well as a generally increased awareness of the breadth and magnitude of disease associated with waterborne and other pathogens.(1–4) This heightened awareness has highlighted the need for the development of methods to assess the risks of human disease due to exposure to waterborne and other pathogens, to assess the efficacy of environmental control measures in reducing risk, and to assess the relative risks of human disease associated with exposure to various disinfection byproducts versus exposure to infectious microorganisms.

Quantitative risk assessment has been a valuable and widely used tool to assess human health effects associated with exposure to chemicals.(5) Information from these assessments has been invaluable to decision makers responsible for developing regulatory standards, assessing treatment requirements, and conducting risk/benefit analyses. While no less important in terms of the assessing the potential for and magnitude of human health effects, the development of an approach to assess the effects associated with exposure to pathogens has received far less attention. The relatively few quantitative assessments that have been conducted for pathogens have generally utilized the conceptual framework that was developed for chemical risk assessments.(6–9) As these risk assessments have been developed, many complexities, some of which are unique to the assessment of risks associated with exposure to pathogens, have been noted.(7–10) For example, a critical consideration for pathogen risk assessments is the potential for changes in pathogen concentration due to growth or death. An analogous problem for chemical risk assessment is changes in chemical concentration as a function of degradation and absorption. Additionally, the distribution of pathogenic microorganisms in water or other media may be heterogeneous due to clumping or aggregation, a problem potentially analogous to heterogeneous concentrations of chemical contaminants in water and other media. However, some complexities are unique to pathogens. For example, secondary or person-to-person transmission is likely to be important for pathogenic microorganisms, but less so chemicals (although secondary spread of radiation and some chemicals may occur, for example, via contaminated clothing). In addition, there is the potential for short- or long-term immunity from some infectious microorganisms. Given these complexities and potential differences from chemical risk assessment, the question has arisen as to whether the conceptual framework developed for chemical risk assessment is appropriate for the assessment of risks of human disease following exposure to pathogens.

To address this concern, the International Life Sciences Institute (ILSI) Risk Science Institute (RSI) in cooperation with the U.S. EPA Office of Water, convened a working group to develop a conceptual framework to assess the risks of human disease associated with pathogenic microorganisms. The working group was not asked to critically evaluate or develop specific analytical methods, but rather to take the opportunity to broadly consider the entire process of risk assessment as applied to waterborne and other pathogens. The working group was asked to consider a number of issues including: (1) the dynamic and iterative nature of the risk assessment process; (2) the role of risk managers, risk assessors, and stakeholders; and (3) the wide variety of potential scenarios such as the risk of human disease associated with pathogens in drinking water, recreational water, or sludge, foods, devices, and other media. Discussions of these issues led to the development of a conceptual framework for pathogen risk assessment which is described below.

2. CONCEPTUAL FRAMEWORK

Pathogen risk assessment is a process that evaluates the likelihood of adverse human health effects occurring following exposure to a pathogenic microorganism or to a medium in which pathogens occur. A conceptual framework for assessing the risks of human disease following exposure to pathogens is shown in Fig. 1. The framework is conceptually similar to the National Research Council (NRC) paradigm for human health risk assessments,(5) as well as the framework for ecological risk assessment developed by the U.S. EPA.(11) The risk assessment process involves three phases: problem formulation, analysis (which includes characterization of exposure and human health effects), and risk characterization (Fig. 1). The three phases of microbial risk assessment are described below.

3. PROBLEM FORMULATION

Problem formulation is the first phase of the pathogen risk assessment. It is a systematic planning step that identifies the goals, breadth, and focus of the risk assessment, the regulatory and policy context of the assessment, and the major factors that will need to be addressed for the assessment. To be meaningful and effective, pathogen risk assessments must be scientifically valid and relevant in both the regulatory and public health contexts. Although risk assessment and risk management are distinct processes, establishing dialogue between risk assessors, risk managers, and potential

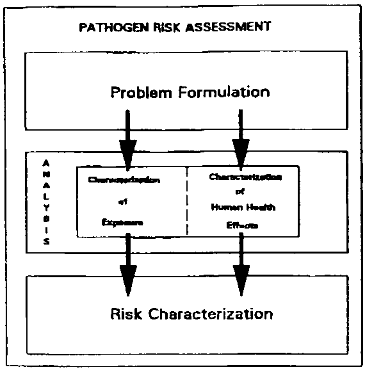

Fig. 1. Generalized framework for assessing the risks of human disease following exposure to pathogens.

stakeholders during the problem formulation phase will ensure that both societal and scientific goals are met.

A risk assessment may be initiated for a variety of reasons. For example, a particular pathogen may be known to occur on food or in water (without a recorded outbreak of disease); thus, it may be necessary to assess the potential for human risk associated with exposure to the pathogen. Alternatively, a risk assessment may be initiated because of an outbreak where the specific pathogen or vehicle of infection (medium of concern) is unknown. Additionally, the risk assessment process may be initiated to determine critical points for control such as watershed protection measures, specific water treatment processes, or food handling activities. The risk assessments developed for each of these situations may be quite different due to the available database, the regulatory context for the assessment, and the socioeconomic drivers for the assessment. Therefore, a critical component of the problem formulation phase is to determine the purpose of the risk assessment, and the unique questions that the assessment is to address.

Once the purpose of the risk assessment is defined, the problem formulation phase then proceeds to an initial characterization of exposure and health effects. A conceptual model is developed that describes the interactions of a particular pathogen or medium and a defined population and exposure scenario. The model also describes the specific questions to be addressed, the relevant information needed, the methods that will be used to analyze the data, and the assumptions inherent in the analysis. This conceptual model provides direction for the analysis phase of the assessment.

4. ANALYSIS PHASE

The analysis phase of the pathogen risk assessment consists of the technical evaluation of data on the potential exposure and health effects, and is based on the conceptual model developed during problem formulation. This phase consists of two elements, characterization of exposure and characterization of human health effects (Fig. 2). Analyses of these two elements, while separate, must be interactive to ensure that the results are compatible (illustrated conceptually by the dotted lines in Figs. 1 and 2). Both the characterization of exposure and the characterization of human health effects are influenced by the analytical methods and/or tools that are available. As information is analyzed with available methods, the analysis in turn provides fuel for the development of more refined methods, which then leads to the refinement of the analysis.

4.1. Characterization of Exposure

Characterization of exposure involves an evaluation of the interaction between the pathogen, the environment, and the human population. Three elements of analysis may be involved: pathogen characterization, pathogen occurrence, and exposure analysis (Fig. 2). Characterization of exposure culminates in the development of an exposure profile that quantifies the magnitude and pattern of human exposure for the scenarios developed during problem formulation and serves as input for the risk characterization.

4.1.1. Pathogen Characterization

Pathogen characterization involves determining the properties of the pathogen that affect its ability to be transmitted to and cause disease in the host. The ability of a pathogen to cause disease is influenced by many factors. Some of these factors relate to the intrinsic properties of the pathogen such as phenotypic and genetic characteristics that influence virulence and pathogenicity, and host specificity. Others relate to the ability of

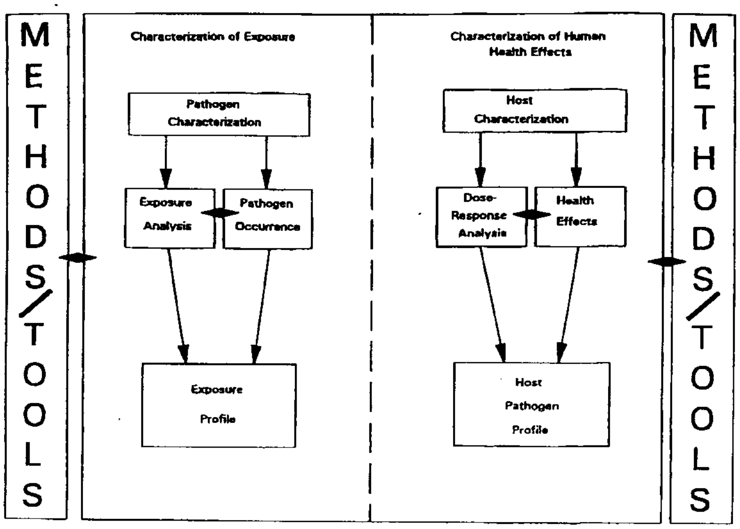

Fig. 2. Analysis phase of the risk assessment framework for pathogens.

the pathogen to survive and multiply in the environment based in part on its resistance to environmental control measures. Environmental controls, in turn, may alter virulence and pathogenicity. Finally, determination of the particular transmission pathways may be important in the determination of route of infection or portal of entry, as well as the potential for secondary spread. The specific characteristics that are evaluated will depend on the scenario that is delineated during problem formulation.

4.1.2. Pathogen Occurrence

Pathogen occurrence involves characterizing the occurrence, distribution, and physical state of the pathogenic microorganism. As part of pathogen occurrence, it may be necessary to determine the concentration of the pathogen in the environmental media of interest and potential sources of the pathogen. Such estimates may be influenced by the physical state of the pathogen in the environment. For example, aggregation or particle association can provide protection from environmental control measures and result in a higher exposure than indicated by analytical results; therefore, a thorough understanding of the niche of a pathogenic microorganism will be important. Also relevant to a determination of pathogen occurrence is information on the ability of the pathogen to survive, persist, and multiply as well as consideration of seasonal differences in occurrence or other temporal distributions. The outcome of the pathogen occurrence step is an evaluation of all relevant factors pertaining to the occurrence and distribution of the pathogen.

4.1.3. Exposure Analysis

Exposure analysis involves characterizing the source and temporal nature of human exposure. Many elements may be included in the analysis. Where possible, the vehicle, such as drinking water, sludge, food, etc., is identified as well as the associated unit of exposure (e.g., number of glasses of water consumed). The size and demographics of the potentially exposed population should be determined. Consideration of the temporal nature or duration of exposure, route of exposure, and transmission potential may also be important. For example, a single oral exposure to certain pathogens with high transmission potential may have substantially different consequences than multiple exposures to pathogens with low transmission potential. Of course, the route of exposure and transmission potential will in turn be influenced by the behavioral characteristics of the potentially exposed population.

4.1.4. Exposure Profile

The exposure profile provides a qualitative and/or quantitative description of the magnitude, frequency, and patterns of exposure for the scenarios developed during problem formulation. The profile draws on information obtained from the pathogen characterization, pathogen occurrence, and exposure analysis phases. A critical component of the exposure profile is an assessment of the assumptions and uncertainties that are made during the analysis. In many assessments, data may not be available for all aspects of the analysis and/or the data may be questionable quality. Consequently, a number of assumptions may be made, each with varying degrees of uncertainty. These assumptions should be based on scientific judgment, and described in the exposure profile for consideration in risk characterization. The uncertainty analysis identifies, and to the extent possible, quantifies the uncertainty associated with each element of the exposure assessment, as described by Finkel(12) and the NRC.(13) This may include quantification of uncertainties associated with errors introduced as a result of study design, errors associated with estimates of the concentration of the pathogenic microorganism, or errors associated with estimates of human ingestion volumes. The uncertainty analysis is described in the exposure profile, providing insight into the strengths and weaknesses of the assessment for consideration in risk characterization.

4.2. Characterization of Human Health Effects

Characterization of human health effects involves the interactive analysis of three critical components: host characterization, evaluation of human health effects, and quantification of the dose–response relationship (Fig. 2). This phase culminates in the development of a host-pathogen profile that provides qualitative and/or quantitative descriptions of the nature of the illness, and quantitative dose response analyses for the scenarios developed during problem formulation, and serves as input for risk characterization.

4.2.1. Host Characterization

Host characterization involves an evaluation of the characteristics of the potentially exposed human population that may influence susceptibility to a particular pathogen. It is important to recognize that host factors may be more important in determining the severity or outcome of an infection than in determining the likelihood of infection. High-risk groups may develop severe symptomatic illness, while low-risk groups develop asymptomatic infections or mild illness. There are many factors that can influence susceptibility and severity, although not all will be important for all pathogens. Age is an important consideration since the risk of disease is often greater for the young and the old. Susceptibility may be influenced by the status of the immune system, and therefore knowledge of immune status, concurrent or recent infections, and use of medications may be important. Other factors that may influence susceptibility include genetic predisposition, pregnancy, and nutritional status. Finally, the analysis may consider whether and how social and/or behavioral traits influence susceptibility or severity.

The outcome of host characterization is the identification of factors that influence susceptibility and severity, and the identification of susceptible subpopulations. Both of these are important for the assessment of health effects.

4.2.2. Health Effects

The clinical illness associated with the pathogen or medium is characterized in the health effects phase. When possible, the characterization should consider the whole spectrum of clinical manifestations including symptomatic and asymptomatic infections, duration of clinical illness, mortality, and sequelae. In most cases, the assessment of health effects will rely on epidemiological and clinical information; animal studies will be of limited use in the assessment of human illness due to the host specificity of most pathogens. Several epidemiological study designs may be employed in the assessment of human illness, and each is associated with certain strengths and limitations. For example, data may be available from a clinical or population experimental epidemiologic study, such as a controlled clinical study to determine infective dose or an intervention study to compare effects of improved water treatment or quality. In these studies, it is possible to control for the health and immune status of individuals, as well as the dose, route, and time of exposure. However, difficulties can be encountered in the extrapolation of these data to a natural setting due to uncertainties associated with small sample size, the degree to which the response of the population studied is predictive of the potential response of the population at risk, and the similarity between the laboratory strain of the pathogen and strains in the environment.

In other cases, data may be available only from outbreaks. These cases provide the opportunity to obtain data in a natural setting, and have many strengths including the ability to assess susceptible subpopulations, seasonality of the pathogen, and secondary transmission. However, they are limited by difficulties in recognizing an outbreak, recognition of the full spectrum of the illness, and lack of knowledge concerning exposure. Regardless of study type, the strengths and limitations of the studies should be considered in the assessment, including evaluations of the statistical power of the study and the appropriate control of systematic bias, especially confounding and misclassification.

Consideration of the severity of the illness associated with a particular pathogen may be important and may be expressed in a variety of ways. Some pathogens may be associated with a high degree of mortality and therefore severity may be expressed as mortality rate. Other pathogens may be associated with gastrointestinal distress and severity may be expressed as the proportion of illnesses. In addition, the potential for long-term illness may exist, in which case severity may be expressed in terms of the cost to society such as the proportion of workdays lost or cost of treatment. When severity is highlighted as a consideration during problem formulation, it is important that the assessment include a definition of the severity scale and how it is measured.

For pathogens that cause long-term chronic illness, it may be desirable to include an assessment of the quality of human life during the illness. Quality of life may be expressed in a variety of ways depending on the nature of the illness. For some pathogens, human life expectancy may decrease, chronic debilitation may occur, or quality of life may be affected by episodic bouts of disease. When included in an assessment, the definition of quality of life should be stated as well as the associated assumptions and uncertainties.

4.2.3. Dose–Response Analysis

This analysis evaluates the relationship between dose, infectivity, and the manifestation of clinical illness (response). This relationship is complex, and in many cases a complete understanding will not be possible. In most cases, animal models will be of limited use due to the host specificity of most pathogens, and therefore, dose–response analyses will generally be based on epidemiological and clinical data. The analysis will be affected by the quality and quantity of data available for the assessment of human health effects, and at least in some cases, knowledge of the actual dose may be limited. For example, human outbreak studies may provide only crude, indirect measures for dose–response assessment such as number of glasses of water consumed. Similar restraints exist for population experimental, cohort, and case-control studies. In situations where the actual dose of microorganisms ingested is known, such as in human feeding studies, there may be uncertainties associated with the use of laboratory strains of the particular pathogen as well as with how predictive the response of a very select test population is of the population at risk. A second difficulty that may be encountered in a dose–response analysis is the availability of data regarding infection. In many cases, infectivity data will not be available, and therefore the analysis may describe the relationship between dose and clinical illness rather than dose, infectivity, and clinical illness.

4.2.4. Host-Pathogen Profile

Using information obtained from the host characterization, the assessment of human health effects, and the dose–response analysis, the host-pathogen profile provides a qualitative and/or quantitative description of the nature and potential magnitude of adverse human health effects for the scenarios developed during problem formulation. A critical component of the host-pathogen profile is an assessment of the assumptions and uncertainties that are made during the analysis. In many assessments, relevant data may not be available for all aspects of the analysis and data may be of questionable quality. Consequently, a number of assumptions may be made based on scientific judgment and these should be described in the host-pathogen profile. The associated uncertainties should be described, and quantified where possible.(12,13) The uncertainty analysis is included in the profile and serves as input for risk characterization.

5. RISK CHARACTERIZATION

Risk characterization is the final phase of the pathogen risk assessment and results from combining the information from the exposure profile and host-pathogen profile. During this phase, the likelihood of adverse human health effects occurring as a result of a defined exposure scenario to a microbial contaminant or medium is estimated. Risk characterization consists of two major steps: risk estimation and risk description. Risk estimation describes the types and magnitude of effects anticipated from exposure to the microbe or medium. All assumptions that were made throughout the risk assessment should be clearly identified, and their impact on the assessment described. The uncertainties associated with problem formulation, analysis, and risk characterization should be identified and quantified where possible. The confidence in the risk estimates should be expressed in the risk description and should include consideration of the sufficiency and quality of the data, and evidence of causality. Finally, the risk characterization should include a discussion of whether the assessment adequately addresses the questions delineated during problem formulation.

6. FUTURE DIRECTIONS

The working group developed a conceptual framework for assessing the risks of human disease following exposure to pathogenic microorganisms in water, on food, or associated with other media. The framework is conceptually similar to the framework developed for chemical risk assessments(9) and ecological risk assessments.(11) The inclusion of a problem formulation phase is similar to the framework for ecological risk assessment, and acknowledges the need for a dialogue between the risk manager, risk assessor, and stakeholders to utilize resources to produce scientifically sound risk assessments that are relevant to management decisions and public concerns. This framework emphasizes the dynamic and iterative nature of the risk assessment process, and allows wide latitude for planning and conducting risk assessments in diverse situations.

Future efforts need to be directed toward the examination of methods for estimating risk, and ways to improve the estimates. For example, recent risk assessments of pathogens in drinking water have been based on a series of probability functions.(6–9) The first step in these analyses is the definition of the probability of infection following ingestion of a pathogen through application of the beta-Poisson or other models. The second step is to ascertain the relationship between infection and the progression to clinical disease. This relationship is described as a conditional probability that once having been infected, a particular individual contracts a disease. An assumption inherent in this second step is that the chance of contracting disease (once infected) is independent of the ingested dose. Further understanding of the relationship between infection and subsequent illness is needed to evaluate the impact of this assumption. In addition, there is a need to develop methods to incorporate the impact of critical susceptibility factors such as age and immune status, which are currently not accounted for. Current risk estimates are also based on the assumption that the probability of infection or illness resulting from one exposure is independent of previous exposures. This assumption ignores the possibility of temporary or permanent immunity, and methods for incorporating such information would greatly improve risk estimates. In addition, methods for incorporating information on secondary transmission are needed. Finally, there is a need to develop methods to account for the heterogeneous distributions of microorganisms and the potential changes in concentration of microorganisms in the environment as a function of growth and death.

ACKNOWLEDGMENTS

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Senate Permanent Subcommittee
on Investigations

EXHIBIT # 9

SUPPLEMENTAL QUESTIONS FOR THE RECORD
SUBMITTED BY SENATOR MAX CLELAND (D-GA)

Hearings Before The
U.S. SENATE PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
July 9, 1998
THE SAFETY OF FOOD IMPORTS: FROM THE FARM
TO THE TABLE – A CASE STUDY OF TAINTED IMPORTED FRUIT

DR. STEPHEN M. OSTROFF
National Center for Infectious Diseases
Centers for Disease Control and Prevention (CDC)

Q1. How many disease outbreaks have been caused by produce grown in the United States? What was the cause of the contamination of these products?

A1. It is difficult to provide a precise answer. As was highlighted in the oral and written testimonies, outbreaks of foodborne disease are often inadequately identified, investigated, and reported, so the existing database is difficult to interpret in quantitative terms and is likely to underestimate the scope of the problem. Produce carries the special burden of a generally short shelf-life, rapidly changing geographic origin, and packaging/retail practices that commonly leave the final user/consumer unaware of its origins. Given these limitations, existing surveillance data suggest that produce is less often a source of foodborne disease than are foods of animal origin. Within the set of outbreaks associated with produce, both domestically produced and imported foods have been implicated.

Produce can be contaminated with disease-causing microorganisms at all points of the continuum from farm to table. Outbreaks of produce-associated illnesses have been linked, at least tentatively, to contamination during growing by use of unsafe agricultural water or animal manures (e.g., on a small farm in New England that was the source of a small cluster of *E. coli* O157:H7 infections), during harvest and processing by use of unsafe processing water and inadequate worker hygiene (e.g., at a field lettuce processing facility in California that was the source of lettuce implicated in an outbreak of *E. coli* O157:H7 infections affecting Illinois and Connecticut in 1996), during retail sale by unsound food handling practices (the retail practice of "freshening" lettuces heads by dunking them in a common water bath was suspected to be the mechanism of contamination of lettuces in an outbreak of lettuce associated *E. coli* O157:H7 infections in Montana in 1996. After two multistate outbreaks of salmonellosis were traced to tomatoes from the same producer in South Carolina, the tomato washing apparatus was re-engineered to include on-line chlorination, to reduce the likelihod of product contamination from processing water), and during preparation by unsound food handling practices (e.g., a recent outbreak of 4,000 enterotoxigenic *E. coli* infections in Illinois was related to a variety of fresh salads, that were prepared in a catering kitchen that had no handwashing facilities).

Q2. When other nations suspect problems with U.S. products, do you work with their investigators to correct the problem? Have other nations banned the import of U.S. products on the grounds that they may be contaminated? Do you consider these bans to be legitimate, or are they simply retaliation for U.S. import bans?

A2. CDC often collaborates with its colleagues in Ministries of Health in foreign countries when they are investigating outbreaks of foodborne illness, whatever the origin of the food, to limit the impact of foodborne disease on Americans traveling overseas and to stop domestic commerce of potentially hazardous foods. Recent examples include Cycloporiasis linked to raspberries in Canada, a botulism outbreak in Argentina, and an outbreak of *E. coli* O157:H7 infections in Japan thought to be associated with radish sprouts. Questions relating to the use by foreign governments of foodborne hazards in foods exported from the United States should be directed to USDA or the Office of Trade.

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 10

SUPPLEMENTAL QUESTIONS FOR THE RECORD
SUBMITTED BY SENATOR MAX CLELAND (D-GA)
Hearings Before The
U.S. SENATE PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
July 9, 1998
THE SAFETY OF FOOD IMPORTS: FROM THE FARM
TO THE TABLE -- A CASE STUDY OF TAINTED IMPORTED FRUIT

DR. JEFFREY A. FORAN
Executive Director, Risk Science Institute
International Life Science Institute (ILSI)

★★★

1. In your testimony, you discussed risk management. What do you think is an acceptable level of risk? Can all risk of contamination be eliminated?

2. In quantitative risk assessment, is the source of the product (domestic or foreign, Europe or Central America) a reasonable factor to consider? Would a risk assessment that included such a factor be in accordance with international trade agreements?

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ILSI RISK SCIENCE INSTITUTE
International Life Sciences Institute

RESPONSE TO
SUPPLEMENTAL QUESTIONS FOR THE RECORD
SUBMITTED BY SENATOR MAX CLELAND (D-GA)

Hearings Before The
U.S. SENATE PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
July 9, 1998
THE SAFETY OF FOOD IMPORTS: FROM THE FARM
TO THE TABLE — A CASE STUDY OF TAINTED IMPORTED FRUIT

DR. JEFFERY A. FORAN
Executive Director, ILSI Risk Science Institute

1. There is no single acceptable level of risk for pathogens, chemicals, or other hazards to human health. Acceptable risk is a societal determination, which may or may not be influenced by perceptions of risk (which can be influenced by the nature of the risk, e.g., whether it is voluntary or involuntary), cost/benefit considerations, the level of risk aversion in the exposed population, whether susceptible sub-populations are of concern, and other considerations. In many cases, all risks associated with contamination cannot be eliminated. In the case of Cyclospora, a full, permanent ban on the import of potentially contaminated fruit may eliminate a particular source. However, there are likely to be other sources of Cyclospora and other pathogens; thus, exposed human populations will continue to face health risks associated with exposure to food- and water-borne pathogens. In these cases, quantitative risk assessments will provide estimates of the nature and level of health risks in exposed populations.

2. The source of a product may provide insight into whether and how much a particular food may be contaminated. However, source information will typically provide qualitative information on contamination. Monitoring is required to characterize quantitatively the level of contamination as well as the types of pathogens that occur on foods. Such quantitative information will be most useful for risk assessments for food-borne pathogens.

I do not possess the appropriate expertise to determine whether risks assessments that include consideration of the source of the product are in accordance with international trade agreements.

1126 Sixteenth St., N.W., Washington, D.C. 20036-4804 • Phone: (202) 659-3306 • Fax: (202) 659-3617 • E-mail: rsi@dc.ilsi.org

Senate Permanent Subcommittee
on Investigations

EXHIBIT # 11

SUPPLEMENTAL QUESTIONS FOR THE RECORD
SUBMITTED BY SENATOR MAX CLELAND (D-GA)

Hearings Before The
U.S. SENATE PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
July 9, 1998
THE SAFETY OF FOOD IMPORTS: FROM THE FARM
TO THE TABLE -- A CASE STUDY OF TAINTED IMPORTED FRUIT

DR. STEPHANIE A. SMITH
Investigator
Permanent Subcommittee on Investigations

★★★

1. You stated that under GATT, the U.S. can only impose standards on growers in other countries if we also enforce the same standards domestically. I am concerned that in order to prevent disease in imported products, we will create bureaucratic hassles for U.S. farmers who are already producing safe food and make it more difficult for them to compete globally. For example, the Guatemalans have agreed to a strict policy regarding the water used for irrigation. Would U.S. farmers be able to meet that standard? What sort of documentation or testing would be required of the farmer?

   ANSWER: Let me clarify my comment regarding the GATT rules and domestic standards. As I understand it, Article III of the GATT requires that imported products be treated no less favorably than domestically produced goods with respect to any laws or requirements. However, the current GATT rules contain an exception (Article XX:b) that permits countries to take measures "necessary to protect human, animal or plant life or health," as long as these do not unjustifiably discriminate between countries where the same conditions prevail or are not a disguised restriction to trade. Therefore, where necessary to protect human, animal or plant health, governments may impose more stringent requirements on imported products than they require of domestic goods. The caveat of this exception is spelled out under the Sanitary and Phytosanitary (SPS) Agreement which states that countries will be permitted to impose only those requirements which are needed to protect health and which are based on scientific principles. In addition, it requires that the procedures and decisions used by a country in assessing the risk to food safety or animal or plant health must be made available upon request by other countries.

   Now to answer your question regarding domestic standards, until the FDA began developing voluntary guidance for the produce industry last fall, no guidance I am aware of was available to produce growers on an industry-wide basis. Since then, at least two industry groups have developed and issued guidance documents. The FDA's draft document, entitled "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables," was released for comment this past April. None of these documents discuss the use of microbiological filters for water. Therefore, considering the expense of this type of filter, which Guatemala now requires be used on its own berry farms, I suspect very few U.S. growers, if any, use microbiological filters.

2. To be enforceable under GATT, would the production standards for growers be product specific, or would they apply to all crops? For example, would the standards for peaches be different from the standards for apples? Would the standards for tree fruits be different from the standards for raspberries?

   ANSWER: The type and specificity of standards is not spelled out in the general GATT agreement. However, the United Nations' Joint FAO/WHO Codex Alimentarius Commission is in the process of developing a set of international standards which may be adopted as domestic standards by individual countries who want to have standards in place and have not developed their own. Some of these standards are product- or commodity-specific, others are more general guidelines or codes of practice.

3. What happened to the farms that were not able to meet the standards for export of fresh berries? Do they continue to export frozen berries, or do they now grow other crops? Do you know what alternative crops the farmers might consider? Might these other crops be safe for export?

   ANSWER: In the case of Guatemala, many of the farms not able to meet the revised Guatemalan standards for producing fresh berries for export have gone out of business. Others only export frozen berries. Still others have switched to other crops, such as lettuce, to be sold locally. Most of the alternative crops do not command the premium price that fresh raspberries do and the cost of shipping food abroad makes exporting less attractive.

   Regarding the safety of other crops exported from Guatemala, until the source and mode of contamination of the fresh raspberries is identified, it is difficult to say with any certainty which other crops may also be at risk. However, as Dr. Herwaldt described earlier, the unique morphology of a raspberry makes the survival of an organism like *Cyclospora* more feasible.

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Senate Permanent Subcommittee
on Investigations

EXHIBIT # 12

Comments for the Record

Hearing on The Safety of Food Imports

July 9, 1998

Permanent Subcommittee on Investigations
Committee on Governmental Affairs
U.S. Senate

Submitted for the record by

Fresh Produce Association of the Americas
30 North Hudgins Street
Nogales, Arizona 85621

Phone: 520-287-2707 Fax: 520-287-2948

The Fresh Produce Association of the Americas (Association), which represents the interests of American companies involved in two-way agricultural trade between the United States and Mexico, commends the chairman of the subcommittee, Senator Collins, for clearly stating at the start of the hearings on the safety of imported foods that she does not intend to indict any country or to single out Guatemala. There have been too many innuendoes and unfounded allegations against imported foods. All efforts, therefore, to obtain fair and accurate information are appreciated. The July 9 hearing did much to establish a record of facts about cyclospora. The subcommittee is to be commended.

The Association, nevertheless, remains sensitive to inquiries on the safety of imported foods because there is a natural tendency to speak in generalities and not differentiate between processed and fresh foods. There also has been a tendency not to recognize the reliability and track record of established importers. Plainly put, not all imports are alike, and neither are importers. It is both unfair to legitimate businesses and unenlightening to the public to discuss the safety of imported foods without drawing distinctions and differentiating various types, sources, and shipper/handlers. For example, forgery and fraud are far easier with smaller quantities of certain types of food imports than with truckloads of fresh produce. Discussions of imported foods, therefore, should be specific rather than general to avoid maligning innocent businesses, persons, and countries.

There have been too many instances of unfair, unjustified, baseless, and vindictive allegations of contamination and of food borne illnesses directed against fruits and vegetables. In reality, fruits and vegetables are not the usual cause of outbreaks. Unfortunately, the limited number of exceptional incidents have been used to create fear and distrust in the public mind in magnitude that is completely out of proportion to reality. Sen. Collins was absolutely correct when she said consumers should not stop eating imported fruits and vegetables.

We also wish to commend Sen. Cochran for his comment that Congress should keep in mind the possibility of retaliation against American agricultural exports if Congress were to create legislation based on politics rather than on science. While our booming economy allows American consumers to buy increasing amounts of exotic or high-quality food from all over the world, American farmers are also heavily involved in exporting. World agricultural trade is important to American farmers, and Congress must be careful that all rules, regulations, standards, and restrictions apply equally and fairly to domestic produce as well as to imports. Otherwise, American farmers will find trade barriers created in retaliation against American agricultural exports.

We question the assertion by Sen. Cochran that America faces some serious problems from imported foods. Cyclospora outbreaks were exceptional and, therefore, were newsworthy. Viewed in perspective, imported foods are no more likely to be contaminated than domestic produce. Today's "global village" may hasten our exposure to uncommon diseases against which we may not yet have developed immunity, but we must also remember that we are no more immune to common salmonella than we are to something we have never heard of before. The solution is not to isolate ourselves in the world from quality fresh produce but to become more aware of what we can do personally and as a society to minimize microbial contaminants as a general matter.

Sen. Lieberman spoke about the low level of inspections of imported foods and about improving the level of protection for imported foods. The Senator used as example the cursory inspection of bananas as an indication of the lack of protection. We would like the Senator to note that as an import commodity bananas are hardly ever mentioned as problems. Bananas can become contaminated by careless handling during food preparation but because bananas are peeled before consumption, they are seldom or ever considered a problem fruit. It also is important to keep in mind that the FDA's resources are best spent inspecting foods that are likely to be contaminated than those that have no record of contamination.

The Senator also should note that the "rate of inspection of imported foods" applies to all types of foods entering through all ports of entry. Fresh produce entering this country through established channels, e.g. Nogales, Arizona; Otay Mesa, California, etc. are sampled and tested on a regular basis by FDA. In addition, the importers are established and known. The best assurance of clean food, therefore, is the combination of established farmer and shipper with a records of good performance that goes back for years. Such people have earned their reputations and are more likely to be able to maintain quality, purity, and wholesomeness of the foods they import than those who may not have a track record or are sporadically involved in trade.

Dr. Stephanie Smith also noted that only two percent of imported foods are inspected. She also should explain that that inspection rate is for all types of foods, including canned, dried, smoked, pickled and otherwise processed foods as well as for pasta, cheese, etc. and fresh fruits and vegetables. There are as many chances for contamination of canned, dried, and processed foods as there are for fresh produce. Pasta can contain rodent feces, dried or canned fruit can contain pesticide residues, and processed foods can contain heavy metal residues as well as insect parts and other foreign matter. When the wide range of possible contaminants and sources are considered, the inspection rate could be viewed as inadequate, but certainly not for fresh produce.

If there is a general concern about the safety of imported foods, in contrast to a specific concern about fresh produce, the hearing should include a much broader discussion of contaminants and should include a wider range of witnesses and experts to discuss all types of imported foods, not just fresh produce.

It is most important and necessary to note that there is no quick way to test for microbial contamination at this time. Dr. Smith and others noted that, for example, tests for cyclospora are inadequate. Even tests for pesticide residues take time and since fresh produce are obviously perishable, tests must be done quickly. FDA, therefore, cannot be faulted for not conducting "more thorough tests." At the present level of technology, FDA and USDA can only perform visual inspections on site, and FDA can do tests for pesticide residues at laboratories. It is unfair to FDA and USDA to criticize them for not having a more thorough inspection system. At today's level of technology, FDA and USDA can look at each box of imported produce and still not detect certain contaminants, e.g. cyclospora. For that matter, FDA and USDA could inspect each and every box of domestic produce and still not detect salmonella by visual inspection. They also will not be able to detect cyclospora.

In his comments, Sen. Durbin made the remark that produce samples taken by FDA in Nogales, Arizona are sent to a FDA laboratory and that the test results are not available for two days. He also asserted that the inspected produce are sent on to their destinations while the FDA tests are being conducted. His information is not consistent with current practices in Nogales among Association members.

In fact, FDA now has test results back in Nogales, Arizona in 24 hours virtually all the time. Furthermore, the sampled shipment is segregated and kept in Nogales until the test results come back. No responsible importer in Nogales will ship produce that has been sampled for pesticide residue testing. Association members have devised effective recall methods but are still willing to hold the produce for one day until the test results become available.. Virtually all Association members can trace their shipments to their customers and recall them if necessary.

The Association commends Dr. Jeffrey Foran for noting that there is a critical "data gap." The scientific and regulatory communities simply do not know enough about certain types of microbial contaminants to make final decisions about controls and prevention at this time. He also noted that more information is needed on the "level of risk reduction" because total elimination of pathogens would be impossible. It would be necessary, therefore, to be able to predict risk. With the level of knowledge now available, however, that is not possible. Incidentally, CDC's Dr. Stephen Ostroff said cyclospora had been detected in Papua, New Guinea in 1970. Nearly 30 years later, we still lack much information, including why only raspberries from Guatemala seem to be affected.

Dr. Foran is also correct in stating that there is a big difference between cost analysis and risk assessment. While we agree with Sen. Durbin that we should err on the side of safety and should not place dollar values on good health, we believe that we do need quantitative risk assessment to avoid using guess work in place of science.

Sen. Durbin called for passage of his bill S. 1465 to create a single, consolidated, independent agency for food safety. While the concept is attractive, we believe the effort would be somewhat similar to rearranging deck chairs on the Titanic. Food safety is better assured by leaving experts to do their work in their own agencies and concurrently increasing the level of coordination and collaboration among them. Putting all the food safety functions in one agency would seem to create a greater risk of non performance, especially if the agency gets caught in a battle among scientists. In contrast, by having several agencies involved, food safety efforts can continue even if one agency is slowed down by scientific debate, court challenges, or legislative oversight. We believe that a small coordinating agency might be appropriate for food safety, but we tend to believe that one powerful, all encompassing agency might create more problems than solve them.

The question of equivalency must be addressed. Too many Senators still seem to believe that a food safety system similar to the authority held by USDA for meat and poultry can be created and applied to fruits and vegetables. To prevent legislative efforts from going in the wrong direction and to stop creating false hopes, the Subcommittee should take up and discuss the issue of equivalency in detail, as well as the issue of international trade and mutual obligations under the WTO. Without a clear understanding that there is no domestic standard to which imports can be held, the false hopes of equivalency will continue and tend to waste the time and energy of the subcommittee.

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ILSI Risk Science Institute
International Life Sciences Institute

STATEMENT OF

DR. JEFFERY A. FORAN

before the

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS
COMMITTEE ON GOVERNMENTAL AFFAIRS
UNITED STATES SENATE

9 JULY 1998

I am Dr. Jeffery Foran, an Environmental Scientist and expert in Quantitative Risk Assessment. I am Executive Director of the International Life Sciences Institute (ILSI), Risk Science Institute (RSI) in Washington, D.C. The **International Life Sciences Institute** is a nonprofit, worldwide foundation established in 1978 to advance the understanding of scientific issues relating to nutrition, food safety, toxicology, risk assessment, and the environment by bringing together scientists from academia, government, industry, and the public sector to solve problems with broad implications for the well-being of the general public. The **ILSI Risk Science Institute** was established in 1985 to advance and improve the scientific basis of ecological and human health risk assessment. RSI works toward this goal through an international program of research, working groups, conferences and workshops, publications, seminars, and training programs. RSI recognizes that public health decisions must be based on the best available science; thus, RSI in all of its activities works toward consensus resolution of complex scientific issues by facilitating discussion and cooperation among scientists from academia, industry, government, and public interest groups.

1126 Sixteenth St., N.W., Washington, D.C. 20036-4804 • Phone: (202) 659-3306 • Fax: (202) 659-3617 • E-mail: rsi@dc.ilsi.org

During the spring of 1996, I attended a buffet luncheon at which a variety of fruit (and other foods) was served. Approximately ten days after the luncheon, I developed acute gastroenteritis and diarrhea. Several other individuals who participated in the luncheon developed similar symptoms, which also included nausea, fatigue, loss of appetite, and weight loss. Upon the discovery of the similarity of symptoms and suspecting a similar disease etiology, we contacted the Washington, D.C. Public Health Commission and subsequently, the Centers tor Disease Control and Prevention (CDC) to investigate the potential for food-related causes of these symptoms.

During the investigation of the nature of these symptoms, I visited my physician to determine what might be causing my illness. My physician did not, at the time, suspect a food-borne illness; rather, he suggested that my fatigue and weight loss might be due to stress and a very hectic schedule. No medication was prescribed during my first visit. After this visit, we began to learn, through the news media, of a food-borne pathogen, *Cyclospora*, which elicited symptoms in exposed individuals that were identical to my own (and others who participated in the luncheon). I recontacted my physician upon learning of the symptoms caused by *Cyclospora* infection and the appropriate treatment (antibiotics) for this infectious disease. The CDC subsequently confirmed the outbreak of Cyclosporiasis in individuals who attended the luncheon. I then received medication and was relatively free of symptoms within 14 days. Subsequently, we learned from the CDC investigation that *Cyclospora* most likely occurred on the raspberries that were served during the luncheon, and that these raspberries were most likely imported to the U.S.

For several years, the ILSI Risk Science Institute has been developing a method to assess the human health risks associated with exposure to food- and water-borne pathogens. The disease outbreak in individuals who attended the luncheon has provided a valuable (although uncomfortable) personal lesson of the value of RSI's work. In 1996, RSI published an article entitled *A Conceptual Framework to Assess the Risks of Human Disease Following Exposure to Pathogens* (Journal of Risk Analysis, Vol. 16, No. 6, pgs 841-848). This framework, which was developed by a group of 30 scientists convened by the ILSI Risk Science Institute, highlights the information that must be gathered to fully understand the health risks posed by exposure to food- or water-borne pathogens. Critical to such an assessment is information on the nature of the pathogen itself (e.g., where it occurs, its life-cycle, its ability to cause disease), the nature of exposure to the pathogen (e.g., temporal and spatial factors), host susceptibility, the health effects caused by the pathogen, severity of disease in the host, the nature of the dose/infectivity/response relationship between the pathogen and the host, and an array of other factors. Unfortunately, much of this information is not available for many pathogens that infect humans and cause disease.

For example, with regard to *Cyclospora* at the time of our outbreak, most physicians and public health experts did not fully understand the nature of the organism, its occurrence, its infectivity, and many other issues necessary to characterize the human health risks associated with exposure to the organism. Even after significant investigation, scientists have still not resolved several critical issues about *Cyclospora*, as well as many other pathogens, such as the nature of the dose/infectivity/response relationship - a key issue in conducting quantitative risk assessment. Stated in a simpler fashion - we did not at the time of the outbreak, and still do not know, how many contaminated raspberries one must eat to become infected, or what concentration of *Cyclospora* oocysts must occur on a single raspberry to result in infection. Clearly, the state-of-the-science is poorly advanced, and likely incapable of supporting a comprehensive and conclusive risk assessment for *Cyclospora*. Similar uncertainties confront the risk assessment community with respect to many other food- and water-borne pathogens such as *Cryptosporidium*, *E. coli*, and *Salmonella*.

Why is risk assessment for pathogens so important? Risk assessment is a process that facilitates the organization of information on health risks posed by exposure to pathogens. Organization of information on health risks is necessary because of the complexity of such information and the likelihood that, without such an organizational process, critical pieces of information leading to an understanding of health risks will be missed. Additionally, the use of risk assessment methods to gather and organize information on health risks facilitates the identification of knowledge and data gaps that must be filled to fully understand and characterize risks. Finally, and most important, a quantitative risk assessment can provide a probabilistic expression of health risks. This information is critical in assessing the efficacy of control technologies, in comparing the benefits of different control technologies, in the conduct of cost/benefit analyses, and in facilitating the development and selection of policy options to manage health risks. Without a quantitative assessment of health risks, we are left with simple guesses as to which control technologies or policies are most appropriate to reduce health risks associated with exposure to food- and water-borne pathogens.

Risk assessment is not a panacea. It will not prevent all human infection and disease. And, without reliable data, or used improperly, it can even provide misleading information. However, when used correctly and conducted with reliable data, risk assessment will provide and encourage the development of information that will lead to informed decision making. It can also provide predictions of potential health risks, which can then be managed before disease occurs in human populations. At its best. it could even play a role in preventing the outbreak of Cyclosporiasis and other pathogen-related diseases. For this reason, adequate resources must be made available to conduct comprehensive risk assessments for food- and water-borne pathogens, and to address the many uncertainties and knowledge gaps that accompany the risk assessment process.

I appreciate the attention of the Committee and will be pleased to answer questions that you may have.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

STATEMENT OF

STEPHEN M. OSTROFF, M.D.

ASSOCIATE DIRECTOR FOR EPIDEMIOLOGIC SCIENCE

NATIONAL CENTER FOR INFECTIOUS DISEASES

CENTERS FOR DISEASE CONTROL AND PREVENTION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

COMMITTEE ON GOVERNMENTAL AFFAIRS

PERMANENT SUBCOMMITTEE ON INVESTIGATIONS

U.S. SENATE

JULY 9, 1998

Good morning. I am Dr. Stephen M. Ostroff, Associate Director for Epidemiologic Science at the National Center for Infectious Diseases, Centers for Disease Control and Prevention (CDC). I am accompanied by Dr. Barbara Herwaldt, also of the National Center for Infectious Diseases. I am pleased to be here this morning to discuss CDC's programs to monitor, prevent, and control foodborne diseases in the United States. I will provide an overview of CDC's foodborne disease surveillance systems and describe cyclosporiasis associated with imported raspberries as an example of our role in outbreak response.

Although the United States has one of the safest food supplies in the world, the public health burden of foodborne diseases is still substantial. The Council for Agricultural Science and Technology has estimated that as many as 9,000 deaths and 6.5 to 33 million illnesses in the United States each year are food-related. Foodborne disease costs the U.S. economy several billion dollars annually. A variety of pathogens and toxins have been described as causes of foodborne disease, and new ones continue to be identified.

In 1997, in response to the growing concern about food safety, the President announced the National Food Safety Initiative. CDC's collaborative involvement with the Food and Drug Administration (FDA), the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency in the ongoing expansion of this initiative responds to the new challenges by building a national early warning system for hazards in the food supply through enhanced capacity for surveillance and outbreak investigations at the State and federal levels. Specific activities of the Initiative include expanding the scope of FoodNet, CDC's active foodborne disease surveillance system, using it to define the true incidence of many diagnosed foodborne infections and to assess their sources and potential for control; developing and standardizing new and rapid diagnostic techniques and molecular subtyping, or fingerprinting, for foodborne pathogens; and designing and delivering training programs for epidemiologists, laboratorians, and health professionals.

Foodborne diseases are common and, in principle, preventable. Some of the causes of foodborne diseases that were formerly problematic are now well controlled by standard prevention strategies, such as pasteurizing raw milk, appropriately managing the canning of food, and ensuring that restaurants and other food preparation areas are clean and well maintained. However, new challenges continue to arise, including the increasing globalization of our food supply, larger scale production and distribution networks, and changing dietary habits; and new efforts are required to address these issues.

Preventing foodborne disease requires a coordinated program of risk assessment and risk management involving Federal, State, and local agencies and non-governmental partners. CDC's primary role in this coordinated effort is to identify foodborne hazards, characterize the risk of foodborne disease, and identify strategies that will prevent additional cases. In 1994, CDC issued a strategic plan, *Addressing Emerging Infectious Disease Threats: A Prevention Strategy for the United States*, which emphasized surveillance, applied research, and prevention activities. An updated version of this plan will be published later this year. As in the 1994 plan, many aspects of the new version of the plan deal with emerging infectious foodborne diseases. The plan complements sections of FDA's 1997 Food Code and the Hazard Analysis and Critical Control Point (HACCP) food safety programs being implemented by FDA and USDA's Food

Safety and Inspection Service (FSIS) and provides a platform from which CDC's role in the National Food Safety Initiative, which was launched in 1997, can be instituted.

Identification of Foodborne Diseases Problems

A person who becomes ill with a foodborne disease may be part of an outbreak or cluster (a group of patients who all have the same illness after consuming the same food) or may have a sporadic illness (an illness that may be an isolated occurrence and not part of a recognized cluster). Usually, investigations of outbreaks can rapidly determine the source and nature of the illness and identify the control measures needed to prevent additional cases. However, sporadic illnesses are often not diagnosed or considered to be foodborne. Even if they are recognized as being foodborne, it is usually impossible, for single cases, to determine which food is the source of the infection. Because individual sporadic cases are far more common than outbreaks, they are a prime target for prevention efforts.

Effective public health surveillance is key to identifying and monitoring the prevalence of foodborne disease. CDC is typically notified of a potential foodborne disease problem by a State or local health department or by an astute clinician or laboratorian who notices an unusually large number of cases of a certain disease. Physician-based surveillance is useful for public health emergencies that require rapid response, such as potentially lethal botulism, where one case could herald an outbreak and immediate public health action is necessary. Clinical laboratories help detect foodborne diseases by tracking the number of times they identify a specific pathogen. Clinical laboratory-based surveillance has identified multiple outbreaks, including a recent multistate outbreak of *Salmonella* Agona infection linked to cereal. State public health laboratories play an important role in further characterizing the strains isolated from ill people, to see whether there are groups of similar pathogens. Taking advantage of recent advances in computer technology and molecular biology, CDC has developed PulseNet, a network of molecular subtyping (fingerprinting) laboratories at State health departments, FDA, USDA, and CDC, which enhances the ability of laboratory-based surveillance to rapidly identify clusters of related foodborne infections of certain pathogens, sometimes scattered over large geographic areas.

Another source of data is CDC's FoodNet, which is conducted in CDC's seven Emerging Infections Program sites developed as part of the 1994 emerging infections plan. The FDA and the Food Safety and Inspection Service (FSIS) of USDA are providing financial assistance and are important collaborators with CDC in this system. The seven active surveillance sites cover about 7.7% of the U.S. population. These sites actively seek out information on foodborne illnesses identified by clinical laboratories, collect information from patients about their illnesses, and conduct investigations to determine which foods are linked to specific pathogens. As data are collected, this surveillance system provides important information about changes over time in the burden of foodborne diseases and will help the agencies evaluate current food safety initiatives and develop future food safety activities.

For these surveillance systems to be effective and for an illness to be identified as caused by a foodborne pathogen, several things must occur. A person who eats contaminated food and becomes ill must seek medical attention or contact the health department. The patient's clinicians must obtain appropriate diagnostic tests. The laboratory results must be reported to the health department. Information must be assessed to recognize a potential outbreak. Often, not all of these steps occur, and sporadic illnesses and outbreaks are not recognized or reported.

Outbreak Investigations

Once an outbreak is detected, the first response is usually from the State or local health department. When necessary, the State or local health department conducts an outbreak investigation. Due to limited resources at State and local levels, not all outbreaks can be investigated and reported. If an outbreak is very large or significant, is thought to involve an unusual pathogen or unexpected food vehicle, affects multiple states or countries, or when preliminary investigations do not reveal a source, CDC will often be invited by the State health departments to participate in the investigation.

When investigating an outbreak of a foodborne illness, public health officials must combine laboratory diagnostic techniques and epidemiologic investigative methods to determine both the causative agent of the illness and the vehicle for its transmission. This involves interviews with patients and comparison of their responses to those of non-ill persons (control subjects) to determine which foods are implicated. If a food is identified as the source of illness, CDC collaborates with FDA or USDA on the investigation and control of the outbreak, based upon which agency regulates the food suspected.

Approximately 400-500 foodborne outbreaks are reported by State health departments to CDC each year, accounting for 10,000 to 12,000 persons with foodborne illness. CDC summarizes the information in these reports through its Foodborne Disease Outbreak Surveillance System. The reports provide useful, detailed information on particular diseases and on the type and severity of outbreaks that occur in various settings, such as nursing homes or schools. Outbreak investigations can lead to effective prevention strategies, as they are often critical in identifying contaminated foods that can then be removed from the marketplace and in elucidating the problems in food production that lead to disease.

Case Study: *Cyclospora cayetanensis*

CDC's role in outbreak investigation is well illustrated by the 1996 and 1997 outbreaks of infection caused by *Cyclospora cayetanensis*, a recently characterized parasite that causes a gastrointestinal illness called cyclosporiasis. This illness is typically characterized by watery diarrhea and other symptoms, such as nausea, abdominal cramps, weight loss, and fatigue. If not treated, the illness can be severe and prolonged. Before 1996, most of the small number of cases of cyclosporiasis in the United States occurred in travelers who had been in developing countries, and only three small U.S. outbreaks had been reported.

When the pattern of *Cyclospora* infections changed in 1996 and health departments noted cases of cyclosporiasis in people who had not traveled overseas, CDC was notified promptly. In mid-May of 1996, health departments in Florida and New York informed CDC that sporadic cases of cyclosporiasis had been identified in their states. At the end of May, health departments in Texas and Canada informed CDC that some people who had attended specific events, such as a party, had become ill with cyclosporiasis. Thus, CDC was notified of "clusters" of cases, which indicated that an outbreak might be occurring. In June, CDC learned of additional sporadic cases and clusters in the eastern United States and Canada.

Ultimately, 55 clusters with a total of 725 cases of cyclosporiasis were reported to CDC by 14 States, the District of Columbia, and two Canadian provinces. The 55 clusters were associated with events that occurred May 3 through June 14, 1996. In addition, 740 sporadic cases that were not associated with identified events or overseas travel were reported, for an overall total of 1,465 cases from 20 States, the District of Columbia, and two provinces. Twenty-two people are known to have been hospitalized, but no deaths are known to have occurred. Because in most foodborne outbreaks, particularly those that involve more than one locality, many affected cases are unrecognized or unreported, the total number of cases of cyclosporiasis that occurred in this outbreak may have been much larger than the officially reported number.

CDC played many roles in the outbreak investigation, including serving as the national reference laboratory for identifying *Cyclospora* in stool specimens and thus confirming that this parasite caused the outbreak. This role was particularly important because many laboratorians had not had experience identifying *Cyclospora*.

Another role CDC played was to help State and local health departments conduct the studies that ultimately implicated raspberries as the food item that had made people sick. This aspect of the outbreak investigation focused on the clusters of cases that were associated with specific events. Health departments interviewed the people who had attended the respective events about what they had consumed and compared the responses of the sick and the well people to see how they differed. CDC assisted in various ways — for example, by helping to design questionnaires, conduct data analysis, and identify important issues that needed to be addressed in the investigations. CDC also assisted some health departments on site with their local investigations.

As more and more clusters of cases were identified, CDC's coordinating role at the national level became increasingly important. CDC sponsored frequent conference calls and a meeting in July 1996 to discuss the findings to date and to help establish priorities for the investigation and future research. Whereas the investigators from individual States and localities focused on their own jurisdictions, staff at CDC repeatedly looked for the patterns that emerged as data from the individual clusters were compiled and analyzed. Fresh raspberries were found to have been served at virtually all the events, and a strong statistical association was found between illness and consumption of raspberries. Although the investigation focused on the clusters of cases, some studies that compared the exposures of sporadic cases and control subjects were also conducted and implicated raspberries.

Another important role played by CDC was that of coordinating public communications as the investigation progressed. CDC helped improve the consistency of the messages that State and local health departments gave to local media. CDC provided a national perspective about the outbreak when interviewed by the national media and published articles in CDC's *Morbidity and Mortality Weekly Report* to rapidly communicate important findings about the investigation to the public health and medical communities.

Once it was determined that raspberries were the food item responsible for illness, the next step was to determine where they had been grown. This traceback process required close coordination with FDA, State and local agencies, and industry. The first steps of the tracebacks entailed determining where the various events took place and where the raspberries that were served had been bought. The raspberries were then tracked from suppliers and distributors back to importers, exporters, and farms of origin, looking for common themes at each step. The available traceback data implicated Guatemala as the common source for the raspberries. By the time Guatemalan raspberries were implicated, Guatemala's spring export season had essentially ended.

Investigators next tried to determine how the raspberries became contaminated. CDC and FDA sent investigators to Guatemala and to Miami, a major port of entry for imported raspberries, to explore possible modes of contamination. We were able to observe how raspberries were grown, picked, sorted, packed, cooled, transported, and inspected. Because no single packing or storage facility in Guatemala, exporter, type of shipping container, shipment, airline carrier, U.S. port of entry or cargo clearance area, importer, distributor, retailer, or food handler was linked to all events for which we had adequate data about the source of the implicated raspberries, we concluded that some practice or attribute common to multiple farms was the most likely explanation for the outbreak.

Although the mode of contamination was not determined, one hypothesis under consideration is that contaminated water may have been used to mix the insecticides, fungicides, and fertilizers that were sprayed on raspberries. Good laboratory methods for detecting low levels of the *Cyclospora* parasite on produce such as raspberries or in water and other environmental samples are not yet available. By the time the clusters of cases were detected, leftover raspberries from the events were not available for testing.

Although the precise mechanism by which raspberries became contaminated was unclear, FDA and CDC provided suggestions to the Guatemalan Berry Commission (GBC) about possible ways to reduce the risk for contamination. The GBC voluntarily implemented various prudent measures to improve water quality and sanitary conditions on farms that were going to export to the United States in subsequent export seasons.

Despite these control measures, another multistate outbreak linked to Guatemalan raspberries occurred in North America in the spring of 1997. CDC learned of this outbreak in early May 1997, when several health departments informed CDC of clusters of cases that were associated with April events. Ultimately, 41 clusters with a total of 762 cases were reported, which were associated with events that occurred April 1 through May 26, 1997, in 13 states, the District of Columbia, and one Canadian province. In addition, 250 sporadic cases were reported for the outbreak period, for an overall total of 1,012 cases in 17 states, the District of Columbia, and two provinces.

Once again, the investigation, which focused on the clusters of cases, implicated fresh raspberries, and Guatemala was found to be the major source of the implicated berries. The outbreak ended shortly after Guatemala voluntarily suspended exportation of fresh raspberries to the United States at the end of May 1997. The fact that another outbreak occurred despite the implementation of various control measures suggests either that the control measures may not have been fully implemented by some farms or that the measures may not have addressed the true source of contamination of the raspberries.

These outbreaks in 1996 and 1997 highlighted challenges related to the investigation of outbreaks of foodborne diseases. Many State and local health departments do not have the necessary infrastructure to conduct outbreak investigations. Also, because *Cyclospora* is an emerging pathogen, most laboratorians lacked the experience and expertise to identify *Cyclospora* in stool specimens, particularly during the 1996 investigation. CDC is developing the capacity to use the Internet to assist laboratories in identifying parasites such as *Cyclospora* in patient specimens. However, many laboratories do not yet have the necessary equipment to take advantage of this technology.

New Challenges--New Opportunities

As we draw to the close of the 20th century, we face new paradigms for foodborne disease due to the globalization of the food supply, the large-scale nature of food production and distribution, and the continuing recognition of new foodborne pathogens. CDC addresses these issues by harnessing the technology of electronic telecommunications and computer systems, developing state of the art molecular fingerprinting techniques, integrating its disease prevention and control activities with food safety programs in FDA and USDA, and building active epidemiologic and laboratory-based surveillance programs in collaboration with our State and local partners. However, much work needs to be done to build the necessary architecture for a truly sensitive and responsive early warning network. Building investigative and laboratory capacity in all of our State partners, enhancing our collaborative activities with international partners where, increasingly, some of our food supplies originate, and improving the qualitative and quantitative understanding of critical food safety problems are important components of CDC's response. CDC has been working with the Council of State and Territorial Epidemiologists and the Association of State and Territorial Public Health Laboratory Directors to enhance core surveillance capacity and to assure that the appropriate architecture exists. A 21st century system is needed to confront 21st century challenges.

Conclusions

In conclusion, strong Federal, State, and local public health surveillance networks are the foundation for rapid identification and investigation of infectious disease threats, including those illnesses that are caused by foodborne pathogens. Foodborne diseases remain a challenge for public health. To address this challenge will require continued investments in our public health infrastructure and strong partnerships among State and local health departments and Federal agencies.

Thank you for the opportunity to discuss the surveillance of foodborne disease. We will be happy to answer questions you or other members of the Subcommittee may have.